Med Tech Reimbursement Consulting

MAPPING THE PATHWAYS ENABLING MARKET ACCESS TO INNOVATIVE MEDICAL PROCEDURES AND TECHNOLOGIES

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This research has been commissioned by MedTech Europe from diagnosis to cure

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.

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EXECUTIVE SUMMARY

Introduction

European countries differ in the way access to medical procedures and medical technologies are provided. Typical payment (reimbursement) mechanisms include a global budget, diagnosis-related groups, and fee-for-service. Some countries (for example, England, Germany, Netherlands, Norway, and Switzerland) have parallel processes of post-reimbursement approval of medical procedures and technologies (funding frameworks). Finally, health technology assessment (HTA) contributes to decision-making about access to technologies. In the project, medical procedures and devices have been considered as separate categories, although they are connected.

Healthcare systems face several challenges in relation to timely access to innovative medical technologies and procedures.

First, while requirements for each process vary in individual countries, the central requirement for the success of the novel procedure or medical technology is good clinical (and often) economic evidence. Development of the required evidence to prove value claims is a time-consuming and costly process. At a certain time, promising technologies have "almost enough" data to gain access, the evidence gap is very limited, and it can be bridged with a focused research effort in the individual country.

Second, there is a constant demand from the medical and patient communities to enable early access to novel medical technologies. Patients are interested in improving their condition, while the medical community also has an interest in medical research.

Third, standard reimbursement frameworks might not have the ability to integrate novel technologies (with proven value) in a timely manner. For example, integration of the novel procedure in the DRG system takes a minimum of four-five years.

Fourth, the availability of access pathways varies for different types of technologies. Healthcare systems are most used to the incorporation of novel procedures and expensive devices, while specific (enabled) access to medical consumables, in-vitro diagnostic tests, and digital technologies might be limited.

These challenges led to the development of two groups of additional (innovative) payment frameworks in several European countries:

- *Unconditional innovation payment*: schemes when reimbursement/funding is provided for technologies with assumed or proven value and no requirement to produce additional evidence;
- *Coverage with evidence development (CED)*: schemes when reimbursement/funding is granted to promising technologies with some evidence gaps, which can be bridged during a limited timeframe of temporary coverage.

MedTech Europe commissioned the development of the report to summarize existing innovative payment schemes and ongoing initiatives to transform healthcare systems to European consulting

company MTRC between July and October 2022. This project is built on a four-year research program in the field of innovation funding, conducted by MedTech Europe. This project is an update, compilation, and enlargement of the knowledge generated in the previous reports commissioned by MedTech Europe. All the information displayed in this report is publicly available.

The objective of the project was to identify and map all the pathways that enable patient access to medical technologies, including the Innovative Payment Schemes (also called Value-Based Access Programs and Accelerated Coverage Pathways for Innovation in previous MedTech Europe projects), and to provide an overview of the concrete/tangible political initiatives/actions aimed at transforming the healthcare systems in European countries.

Medical innovations and their role in the context of the project

While the terms "innovation", "innovation funding", and "innovation payment schemes" are widely used in the context of this project, there is no universal definition of innovation that was considered.

In a broad sense, innovative payment schemes support medical technologies and procedures which do not fit well or do not meet the criteria for the existing reimbursement and funding frameworks.

It means that sometimes when an adequate payment mechanism is established, an innovation can immediately fit well into the existing system (e.g., payment via diagnosis-related groups), so no accelerated pathway is necessary.

Many of the schemes identified in the report do not define innovations. Rather, they establish inclusion and exclusion criteria, which are based on the priorities of healthcare systems.

As objectives of the schemes differ, the inclusion criteria vary significantly, including the proven cost-saving effect (e.g., for the MedTech Funding Mandate in England), lack of comparator indicating a high unmet need (e.g., for pre-LPPR provisional pathway in France), lack of sufficient clinical data while offering a promising effect on patient outcomes.

While identified schemes, in general, do not define innovations, some common themes include benefits to patients and healthcare systems, novelty on the market, and use in new clinical indications.

The methodology of the project included a screening of the websites of the relevant payer and decision-making stakeholders in European countries, the use of MTRC in-house knowledge, collecting feedback from MedTech Europe members

Healthcare systems are evolving, and existing processes might change over time, or new processes will emerge. The results of the report should be interpreted with caution; validation of the status of the innovative payment schemes and their requirements should be made before applying for inclusion in these schemes by the users of the report.

Summary

To date, only a limited number of European countries have been able to introduce and administer innovative payment schemes: Austria, Belgium, England, France, Germany, the Netherlands, Spain, and Switzerland.

Indeed, out of the 32 European countries that were screened, 24 did not possess any innovative payment schemes, and a total of 21 schemes were identified in the eight European countries listed above, with 13 in England, France, and Germany alone (table below). At least two additional programs have been announced, but operational data are currently lacking: a reimbursement model for digital technologies in France and a program in Scotland.

Country	Innovative Payment Scheme	Type
Austria	Provisional Codes for New Diagnostic or Therapeutic Methods (Neue Untersuchungs- und Behandlungsmethoden, NUB)	CED
Belgium	Restricted Clinical Application for Devices (Application Clinique Limitée / Beperkte Klinische Toepassing)	CED
Belgium	Temporary Reimbursement of Software Applications (level 3-)	CED
England	Artificial Intelligence in Health & Care Award England (Phase 4)	CED
England	Innovation competition at the NHS Cancer Programme	CED
England	Medtech Funding Mandate	Unconditional innovation payment
France	Article 51 of the Social Security Financing Act	CED
France	Health Economic Research Program (Programme de Recherche Medico-Economique, PRME)	CED
France	Innovation Funding (Forfait Innovation)	CED
France	List of Biological and Anatomocytopathology Innovative Acts (RIHN) / Supplementary List	CED
France	Provisional Registration of Medical Procedures (Prise en Charge Provisoire) (provisional registration in the CCAM classification)	CED
France	Transitional Coverage of Medical Devices (Prise en Charge Transitoire) (pre-LPPR List registration)	Unconditional innovation payment
Germany	G-BA Innovation Fund (Der Innovationsfonds beim Gemeinsamer Bundesauschuss, G-BA)	CED

Country	Innovative Payment Scheme	Type
Germany	Government Co-Funded Clinical Studies (Erprobungsstudie) ((§137e framework)	CED
Germany	Innovation Funding for New Diagnostic or Therapeutic Methods (Neue Untersuchungs- und Behandlungsmethoden, NUB)	Unconditional innovation payment
Germany	Provisional listing of Digital Health Applications (DiGA)	CED
Netherlands	Small-Scale Experiments for the Introduction of Innovations (Innovatie voor kleinschalige experimenten)	CED
Netherlands	Subsidy Scheme for Promising Care (Subsidieregeling Veelbelovende zorg)	CED
Spain	Monitoring studies of methods, technologies, and procedures (Estudios de de monitorización de técnicas, tecnologías y procedimientos)	CED
Spain	Supervised Use of methods, technologies, and procedures (uso tutelado de técnicas, tecnologías y procedimientos)	CED
Switzerland	Provisional reimbursement of medical procedures (Leistungen in Evaluation)	CED

Note: CED – coverage with evidence development. Reimbursement model for digital technologies in France and a program in Scotland are in development.

The leaders in innovative payment schemes are France (n=6), Germany (n=4), and England (n=3). Belgium, the Netherlands, and Spain have two active programs each. In each Austria and Switzerland, there is only one active scheme. However, the number of innovative payment schemes in individual countries does not reflect the ability for the introduction of innovations in the countries or the attractiveness of the country from a market access perspective.

The majority of the innovative payment schemes (n=15, 71%) focus exclusively or non-exclusively on medical procedures; 12 (57%) cover medical devices, 10 programs (48%) can cover in-vitro diagnostic tests, and nine programs (43%) can cover digital technologies. Although percentages for some types of medical technologies are high, it does not mean that every technology of this kind can easily be accepted for individual relevant schemes given that specific inclusion criteria apply.

The majority (86%) of innovative payment schemes offer support for a small number (<15 annually) of technologies/procedures. One scheme admits between 15 and 50 projects annually (Article 51 of the Social Security Financing Act in France); two schemes admit more than 50 projects annually (G-BA Innovation Fund and NUB in Germany).

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

Some identified schemes did not have any new entrants in the latest years. However, as the schemes were still present in the legislation, it was decided to keep such schemes in the report.

Special attention shall be paid to the initiatives in relation to two innovative payment schemes in the roll-out phase:

- France: Early Coverage framework for innovative digital medical devices;
- Scotland: Accelerated National Innovation Adoption (ANIA) Pathway.

Unconditional innovation payment

The first and rarer category of frameworks is the category of unconditional innovation payment.

To date, only a limited number of such schemes exist: MedTech Funding Mandate in England, the recently introduced transitional coverage for medical devices program (pre-LPPR) in France, and NUB in Germany.

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. However, there, of course, could be entry requirements for such schemes.

Coverage with evidence development (CED) schemes

Coverage with evidence development is a more common category of innovative payment schemes in Europe.

One typical pre-requisite for CED schemes is a complex reimbursement/funding process with high evidence requirements in a given country. Another typical pre-requisite is the high economic capacity of the country, with the possibility of funding technologies with evidence gaps (the average GDP per capita of countries with CED schemes is €56,141, according to the World Bank[1]).

Some discovered CED schemes are strictly connected to existing reimbursement/funding processes and can be activated only as a result of failed or not fully satisfying reimbursement/funding application: NUB in Austria, Limited Clinical Application in Belgium, partly 137e Trial Regulation in Germany, partly monitoring studies in Spain, and provisional reimbursement scheme in Switzerland. By definition, only a very limited number of procedures/technologies are enrolled in such schemes (as there is a rather limited number of reimbursement applications annually).

Other CED schemes allow technologies prior to reimbursement/funding application: most programs in France (including PRME and Innovation Funding (Forfait Innovation)), partly 137e Trial Regulation, G-BA Innovation Fund in Germany, small-scale experiments in the Netherlands, supervised use of technologies in Spain. Such CED schemes typically (but not always) enrol a higher number of procedures/technologies in comparison to CED schemes reviewed above.

[1] Link to the World Bank page

Ongoing initiatives to transform healthcare systems

Healthcare systems are not static. In the report, 33 ongoing initiatives to transform health care systems were identified. The scope of the initiatives varied from the reform of the procedure coding systems in Belgium and Italy to the introduction of the novel payment system in Switzerland.

The largest number of initiatives was identified in the UK (n=6, including two initiatives related to England only and one related to Scotland only), Belgium (n=4), France, and Italy (n=3 each). Other countries with identified initiatives include the Czech Republic, Denmark, Estonia, Finland, Germany, Greece, the Netherlands, Norway, Poland, Portugal, Slovakia, and Switzerland. One initiative relates to the Nordic region (relevant to five countries, including Denmark, Finland, Iceland, Norway, and Sweden).

Call to action

In Europe, reimbursement and funding of medical procedures and technologies are conceived and provided independently by each country. Every country has its specific system resulting from its own particular political, administrative, and constitutional structure and this has led to, amongst others, a significant disparity across European countries in the number and use of pathways that enable timely market access to innovative medical technologies (digital health technologies, medical devices, in vitro diagnostics) and medical procedures.

All European patients need early access to these promising technologies and procedures to improve their quality of life. These pathways also benefit the providers and healthcare professionals (by improving effectiveness, quality of care and clinical outcomes), the healthcare systems and payers (by optimising the use of healthcare resources and providing societal value). Finally, they encourage the industry to develop new technologies.

With this project, a mapping of all the pathways enabling market access to innovative medical procedures and technologies has been developed through the screening of the situation in 32 European countries between July and October 2022.

Its goal was to give an overview of 1) all the current payment schemes for innovative digital health technologies, medical devices, in vitro diagnostics and medical procedures and 2) the current concrete political initiatives aimed at transforming healthcare systems and/or reimbursement and funding systems already implemented by some European countries.

As previously indicated, to date, only one fourth of the screened countries have introduced and administer innovative payment schemes covering digital health technologies, medical devices, *in vitro* diagnostics, or medical procedures. It is however essential to note that the existence of (a) scheme(s) in a country is not automatically a guarantee of improved and timely access to medical technologies as only those schemes which are adequately designed, implemented and managed will offer such access.

In terms of political initiatives aimed at transforming healthcare systems and/or reimbursement and funding systems, the screening has shown that even if several countries are indeed taking concrete initiatives in this direction, the overall political commitment to change the systems remains limited.

To enable improved and timely access to promising digital health technologies, medical devices, in vitro diagnostics and medical procedures, appropriate coverage schemes must be developed, implemented and administrated across all European countries. In addition, timely and ambitious political initiatives focused on improving healthcare systems' quality and delivery of care through optimal reimbursement and funding mechanisms must be put in place in these countries.

By completing the mapping of European countries having pathways enabling market access to innovative medical procedures and technologies, the first step in this direction has been made. Now is the right time to work together on defining an action plan to :

- Clarify what works well and what needs to be improved in the current coverage schemes and political initiatives. Indeed, as indicated before, the mere existence of scheme(s) or initiative(s) is not automatically a guarantee of improved/faster access given that some of these schemes/initiatives might not be appropriately designed, implemented or administrated
- Identify the reasons behind these successes and shortcomings,
- Establish best practices for developing, implementing and running optimal/adequate scheme(s) or initiative(s) for improved/faster patient access to innovative medical procedures and technologies.

MedTech Europe is calling on all key European decision-makers including policy-makers, national and regional payers having responsibilities in this area to join this endeavour. It is crucial to ensure a commitment to safeguarding reimbursement and equitable patient access to innovative value-added digital health technologies, medical devices, and *in vitro* diagnostics. Therefore, it is crucial to implement throughout all European countries holistic pathways which are appropriate to medical technologies, reward their reimbursement and funding in line with the value provided and ensure their uptake .

Other

Access to and spread of innovations is not achieved exclusively via innovative payment schemes. There are different types of other activities, including the selection and prioritisation of innovative technologies by national and regional decision-makers and payers. Such activities were not the primary focus of the report, but when identified, they were reported in the list of irrelevant schemes and activities.

Such activities, include:

- Elective recovery tech fund in England;
- Incentive Scheme for E-Health at Home in the Netherlands;
- Orderly introduction of medical technologies at the regional level in Sweden;
- Regional Innovation Funds in Norway and Sweden;
- Scotland Innovates project;

- Programs of the Bevan Commission in Wales.

The interested reader can explore the possibilities of these pathways further.

SUMMARY IN THE TABULAR VIEW

Element	Austria	Belgium	England	France	Germany	Netherlands	Spain	Switzerland
Number of active schemes	1	2	3	6	4	2	2	1
Number of CED schemes	1	2	2	5	3	2	2	1
Number of unconditional innovation payment schemes	0	0	1	1	1	0	0	0
Eligibility of schemes for medical procedures	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Eligibility of schemes for medical devices	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Eligibility of schemes for in-vitro diagnostic tests	No	No	Yes	Yes	Yes	Yes	No	Yes
Eligibility of schemes for digital technologies	No	Yes	Yes	Yes	Yes	Yes	No	No
Care settings	Hospital	Any	Any	Any	Any	Any	Any	Any

Element	Austria	Belgium	England	France	Germany	Netherlands	Spain	Switzerland
Additional vs existing reimbursement	Existing	Additional	Mixed	Mixed	Additional	Additional	Additional	Existing
Number of awarded procedures*	Limited	Limited	Limited	Varies by scheme: from limited to moderate	Varies by scheme: from limited to large	Limited	Limited	Limited
Possibility to apply directly**	No	No	Yes/No	Yes	Yes	Yes	No	No
Number of non-active schemes	0	0	3	1	0	1	0	0
Number of ongoing initiatives to transform healthcare systems***	0	4	2	3	2	1	0	2

* Number of awarded procedures: limited – less than 15 in total per year, moderate – about 15-50 per year, large – more than 50 per year.

** Application can be made either by industry or by physician / provider / researcher.

*** Number of ongoing initiatives to transform health care systems in other countries: Three each in Italy and the UK (excluding the two mentioned in the table above regarding England, and one specifical in Scotland), two each in Norway and Slovakia, one each in the Czech Republic, Denmark, Estonia, Finland, Greece, the Nordic region, Poland, Portugal, and Scotland.

Note: No active innovative payment schemes within the scope of the project were identified in Bulgaria, Croatia, the Republic of Cyprus, the Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, the Republic of Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Northern Ireland, Norway, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, Sweden, and Wales.

SUMMARY 2 IN THE TABULAR VIEW

Country	Scheme	Type of covered technologies	Applicable care settings	Number of annually awarded projects	Year of the first awarded project	Year of the last awarded project	Application by industry possible?	Application by physician / provider / researcher possible?
Austria	Provisional Codes for New Diagnostic or Therapeutic Methods (NUB)	Procedures	In-patient	Less than 15	2009	2022	No	No
Belgium	Restricted Clinical Application for invasive medical devices and implants	Procedures, devices	In-patient, out-patient, home-care (rarely)	Less than 15	2015	2019	No	No
Belgium	Temporary Reimbursement of Software Applications (level 3-)	Digital health technologies	Home-care, in-patient (rarely), out-patient (rarely)	Less than 15	2022	2022	No	No
England	Artificial Intelligence in Health & Care Award England (Phase 4)	Digital health technologies	In-patient, out-patient, home-care	Less than 15	2020	2021 (2022 results soon)	Yes	Yes
England	Innovation competition at the NHS Cancer Programme	Procedures, devices, IVD tests, digital health technologies	In-patient, out-patient, home-care	Less than 15	2022	2022	Yes	Yes
England	Medtech Funding Mandate	Devices, IVD tests, digital health technologies	In-patient, out-patient, home-care	Less than 15	2020	2022	No	No

Country	Scheme	Type of covered technologies	Applicable care settings	Number of annually awarded projects	Year of the first awarded project	Year of the last awarded project	Application by industry possible?	Application by physician / provider / researcher possible?
France	Article 51 of the Social Security Financing Act	Procedures, devices	In-patient, out-patient, home-care	Between 15 and 50	2018	2022	Yes	Yes
France	Health Economic Research Program (PRME)	Procedures, devices	In-patient, out-patient (rarely)	Less than 15	2013	2021	No	Yes
France	Innovation Funding (Forfait Innovation)	Procedures, devices, IVD tests	In-patient, out-patient	Less than 15	2014*	2021	Yes	Yes
France	List of Biological and Anatomocytopathology Innovative Acts (RIHN) / Supplementary List	IVD tests	In-patient, out-patient	Less than 15	2015	2022	No	Yes
France	Provisional Registration of Medical Procedures	Procedures	In-patient, out-patient	Less than 15	2022	2022	No	Yes
France	Transitional Coverage of medical devices	Devices	In-patient, home-care	Less than 15	2022	2022	Yes	No
Germany	G-BA Innovation Fund	Procedures, IVD tests	In-patient, out-patient, home-care	More than 50	2016	2021 (2022 results soon)	No	Yes
Germany	Government Co-Funded Clinical Studies (§137e framework)	Procedures, IVD tests	In-patient, out-patient	Less than 15	2018**	2022**	Yes	No
Germany	New Examination or Treatment Methods (NUB)	Procedures, devices, IVD tests	In-patient	More than 50	2005	2022	No	Yes

Country	Scheme	Type of covered technologies	Applicable care settings	Number of annually awarded projects	Year of the first awarded project	Year of the last awarded project	Application by industry possible?	Application by physician / provider / researcher possible?
Germany	Provisional listing of Digital Health Applications (DiGA)	Digital health technologies	Home-care, out-patient	Less than 15	2020	2022	Yes	No
Netherlands	Small-Scale Experiments for the Introduction of Innovations	Procedures, IVD tests, digital health technologies	In-patient, out-patient, home-care	Less than 15	2012***	2022****	No	Yes
Netherlands	Subsidy Scheme for Promising Care	Procedures, devices, IVD tests	In-patient, out-patient, home-care	Less than 15	2020	2022	Yes	Yes
Spain	Monitoring Studies of Methods, Technologies, and Procedures	Procedures, devices	In-patient, out-patient (rarely), home-care (rarely)	Less than 15	2015	2020	No	No
Spain	Supervised Use of Methods, Technologies, and Procedures	Procedures, devices	In-patient, out-patient (rarely), home-care (rarely)	Less than 15	2000	2010	No	No
Switzerland	Provisional reimbursement of medical procedures	Procedures, devices (aids), IVD tests	In-patient, out-patient, home-care	Less than 15	2004*****	2022	No	No

* 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 website of the Federal Office for Public Health is from 2004.

METHODOLOGY

Objective and scope

The project aims to identify and map all the pathways that enable patient access to medical technologies, including the Innovative Payment Schemes (also called Value-Based Access Programs and Accelerated Coverage Pathways for Innovation in previous MedTech Europe projects) and the concrete/tangible political initiatives/actions aimed at transforming the healthcare systems in European countries.

What is an innovative payment scheme?

For the purpose of this report, a combination of the high-level definition and a set of exclusion criteria were used to define an innovative payment scheme.

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 or 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 payers, or supports the introduction of the technology;
- Provides funding for typical research and development or applied research activities;
- Represents a procurement activity.

Further information about the taxonomy of the innovative payment schemes is provided in MedTech Europe reports "Taxonomy of Value-Based Access Programmes – Funding for Innovation (Guidance)" (reference) and "Taxonomy of Accelerated Coverage Pathways for Innovation (ACPIs)" (reference).

The following types of technologies were considered:

- In Vitro Diagnostics (IVDs);
- Medical Devices (MDs);
- Digital Health technologies (DHTs) and combinations thereof.

The project considered the following frameworks and schemes:

- Innovative payment schemes are bi-lateral (e.g., payer & manufacturer) or multi-lateral (e.g., payer, provider, manufacturer) agreements that provide *temporary* coverage and/or funding to enable patient access to medical technologies and procedures outside the general reimbursement and funding frameworks. Such schemes are typically payer-driven alternatives to the traditional reimbursement pathways, supporting the accessibility of innovative medical technology solutions. The mapping must include an update of all the IPSs/VBAPs/ACPIs for medical technologies identified via the projects conducted previously by MedTech Europe (i.e., the new schemes/programs/pathways developed/implemented since then, those discontinued, etc.). Should some schemes/programs/pathways be in development but not yet implemented, those have been included in the mapping;
- Although MedTech Europe mainly focuses on regulated medical technologies (CE marked), the particularity of certain digital health technologies does not allow them to pass through regulation pathways and processes (ex., teleconsultation platforms). Therefore, for the scope of this project, non-CE marked digital health technologies, which are recognised as medical technologies within National healthcare systems (i.e., being reimbursed/financed), were also included in the scope of the project. As to mitigate the risk of involving a very broad number of technologies, the project focused on only public funding schemes and pathways for innovation/reimbursement;
- An overarching barrier to patient access to medical technologies is the lack of political commitment to change healthcare (medical technology) funding. The mapping/screening included all the (ongoing and planned) political initiatives/actions aimed at transforming the health care systems and funding and reimbursement of all digital health technologies, medical devices, and IVDs and combinations thereof;
- In case other types of pathways exist (or are in the process of being created) for the funding and reimbursement of digital health technologies, medical devices, and IVDs and combinations thereof, these were included in the mapping.

The following *exclusion criteria* were applied for the innovative payment schemes:

- The scheme represents a standard reimbursement or funding framework;
    - Examples are clinical commissioning policies by NHS England and the "New methods" framework in Norway
- The scheme does not have a connection to reimbursement or funding;
    - However, such schemes were considered in the list of excluded schemes (Appendix 2)
- One-off activities or multi-year activities without new entrants on a regular basis;
    - Such activities were considered as individual projects and not as continuous frameworks
    - One example is the GenomeDE project in Germany

- The scheme does not provide reimbursement or funding for medical technology but for associated activities (e.g., training);
    - One example of such a scheme is the Rapid Uptake Products framework and Pathway Transformation Fund in England
- The scheme does not provide *temporary* reimbursement or funding but speeds up access to regular reimbursement or supports priority decisions by the payers, or supports the introduction of the technology;
    - Such schemes were reported in the list of excluded schemes
- The scheme provides funding for typical research and development or applied research activities;
- Procurement schemes and pathways.

The rationale for excluding schemes from the report is provided for each excluded program in Appendix 2.

The following *exclusion criteria* were applied for ongoing/planned activities to transform healthcare systems:

- The legislation, framework, or activity has been in place for more than six months;
- The activity does not concern financial, coverage, or health technology assessment aspects of market access for medical technologies;
- The legislation does not translate into concrete/tangible plans.

The following countries were included in the scope of the project: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and Switzerland.

Methodology

European Med Tech and IVD Reimbursement Consulting Ltd. (hereafter MTRC) utilised the following methodology (table).

Method	Specifications
Review of the websites of policy-making, reimbursement, funding, and decision-making organisations (screening)	The focus of the search is on both existing schemes and political initiatives for the change of the healthcare systems. The list of monitored organisations is presented in Appendix 1.
In-house expertise	MTRC continued with annual updates of the 2018 Innovation funding report and kept track of all important developments in the field MTRC also performs weekly screening to detect key reimbursement developments in 13 EU markets (Austria, Belgium, Denmark, England, Finland, France, Germany, Italy, the Netherlands, Norway, Spain,

Method	Specifications
	Sweden, and Switzerland) through its paid Reimbursement Alerts service
Input from MedTech Europe's members	Throughout the project, input has been collected from MedTech Europe's members

All the information displayed in this report is publicly available.

The report includes the following key outputs:

- Detailed overview of the selected innovative payment schemes (core section of the report);
- List of ongoing initiatives to transform the healthcare systems;
- List of monitored organisations (Appendix 1)
- List of excluded schemes – schemes that were considered but deemed ineligible for inclusion in the core section of the report (Appendix 2);
- List of inactive schemes (Appendix 3).

The following information was provided in relation to every innovative payment scheme included in the report:

- Title (in national and English languages)
- Objective
- Overview (including budget allocated, the role of HTA, duration of the scheme, and explanation of what happens when the scheme is over)
- Care settings
- Type of covered technologies
- Inclusion criteria
- Applicant
- Stakeholders involved (including the administrator and evaluator)
- Role of the industry
- Clinical and economic evidence requirements
- Statistics and trends about the use of the scheme
- Reference

The role of real-world evidence was specifically considered in the context of the report, but for the majority of the identified innovative payment schemes, no specific RWE requirements have emerged.

The sustainability criterion for schemes was not specifically considered in the report. In general, the presence of such a requirement was not observed in the requirements for individual schemes due to their very nature (narrow focus on several technologies versus broad focus on sustainability of the healthcare system). All relevant criteria are provided for individual schemes in the report.

NB! Information in most of the sections is provided as of July 01, 2022. As the situation is changing rapidly in relation to identified schemes or ongoing political initiatives, the reader should seek up-to-date information, when appropriate.

AUSTRIA: INTRODUCTION

Austria has one active innovative payment scheme: Provisional Codes for New Diagnostic or Therapeutic Methods (NUB), which is focused on medical procedures delivered in hospital settings.

AUSTRIA: PROVISIONAL CODES (NUB)

Title

Provisional procedure codes for new diagnostic or therapeutic methods (Neue Untersuchungs- und Behandlungsmethoden; NUB).

Objective

The objective of the program is to provisionally include innovative medical procedures for which clinical evidence is insufficient into the basic insurance package while the clinical program is ongoing and new clinical data are expected within several years. The coverage provides sufficient reimbursement to cover the cost of the procedure, but the coverage is insufficient to incentivise the use of the procedure, and no specific clinical study is activated. Nevertheless, this program is classified as coverage with evidence development (CED) scheme.

Overview

In Austria, the introduction of a new procedure code requires a good level of evidence. Hospitals make applications to the Federal Ministry of Social Affairs, Health, Care, and Consumer Protection (BMSGPK), and applications are assessed by the LKF-Working Group, which provides evaluations and suggestions to the Federal Health Commission (BGK). During the evaluation process, the LKF-Working Group can request decision support through health technology assessment (HTA) reports from the central HTA body in Austria, the Austrian Institute for Health Technology Assessment (AIHTA). The BGK makes the final decision about the creation of new procedure codes.

Since 2009, it has been possible to include high-cost and innovative procedures in the procedure catalogue despite insufficient evidence via a provisional procedure code. Creating a provisional procedure code is the outcome of a standard application for a new procedure code in case a procedure is promising, but the evidence is regarded as insufficient by the AIHTA and LKF-Working Group.

Provisional procedure codes are grouped into existing DRGs and assigned the same DRG points as comparable treatments. This means that while the procedure is coded using the provisional code, it receives insufficient reimbursement to cover the full cost, which does not create an incentive to use the procedure.

If sufficient evidence is established by November 30th, a re-assessment takes place by the AIHTA. In case of approval by the BGK, the provisional code will be adapted into the DRG system, and a reimbursement tariff will be set, which will be available on January 1st of the following year. If evidence is still not sufficient, the provisional procedure code can be extended for another year. Codes often stay in their provisional state for several years.

Provisional codes are included in the Austrian DRG system (LKF Modell) and are available to all hospitals that obtain approval to use them from the state sickness funds.

Provisional codes are listed in chapter 22 of the BMSGPK catalogue for medical procedures.

Care settings

In-patient settings. The scheme covers hospital procedures.

Type of covered technologies

Medical procedures. Typically, included procedures involve the use of expensive and invasive medical devices.

Inclusion criteria

For procedures to be included in the catalogue, all the following criteria generally must be met:

- The procedure is newly developed;
- The procedure is professionally and clinically accepted in Austria or other European countries;
- There is a clearly defined medical indication for the procedure;
- The procedure is clearly defined and distinct from other procedures;
- The procedure is economically relevant (in terms of cost and frequency);
- There is adequate scientific evidence.

In cases where evidence about the patient-benefit of the procedure, measured using the patient-relevant outcomes in high-quality studies, is insufficient, but there is an ongoing clinical program that can generate additional data to inform decision-making, the procedure can be integrated into hospital care using a provisional code.

Applicant

Hospitals make applications for new procedure codes. The application does not specifically concern conditional reimbursement, which is one of the potential outcomes of the evaluation.

Stakeholders involved

Stakeholder	Role
Federal Ministry of Labor, Social Affairs, Health, Care and Consumer Protection (BMSGPK)	The administrator of the DRG system collects proposals for new procedure codes and releases an updated catalogue of procedures annually
The LKF-Working Group	Assesses proposals, performs evaluations, and makes suggestions to BGK

Stakeholder	Role
Federal Health Commission (BGK)	The body of the Federal Health Agency (BGA) decides upon the creation of new procedure codes
Austrian Institute for Health Technology Assessment (AIHTA)	Central HTA body in Austria. Prepares health technology assessment (HTA) reports on request by the LKF-Working Group

Role of the industry

The industry has no direct role in the application or selection process.

Clinical and economic requirements for the scheme

The assessment of the proposals for new procedure codes is performed according to the inclusion criteria mentioned above. To receive conditional reimbursement, a procedure in scope should have a certain evidence level (even at the RCT level), which is, however, insufficient to prompt the inclusion of the code into the system permanently.

Statistics and trends about the use of the scheme

As of July 1, 2022, there are 14 provisional procedures in the DRG system.

Code	Name of procedure
XN030	Implantation of a stent-graft in the ascending aorta (LE = per session)
XN050	Implantation of a mitral valve clip - percutaneous (LE = per session)
XN051	Implantation of a tricuspid valve clip - percutaneous (LE = per session)
XN055	Replacement of the mitral valve - catheter-assisted, transapical (LE = per session)
XN080	Percutaneous transluminal angioplasty (PTA) on intracranial vessels (LE = per session)
XN090	Percutaneous transluminal recanalization with stent implantation on intracranial vessels (LE = per session)
XN100	Percutaneous transluminal embolization of cerebral aneurysms using a flow diverter (LE = per session)
XN110	Implantation of a permanent embolic protection system in the left atrial appendage (LE = per session)
XN120	Implantation of a completely bioabsorbable stent in the coronary vessels (LE = per stent)
XN130	Implantation of a leadless pacemaker - percutaneous (LE = per session)
XN140	Implantation of a system for telemedical monitoring of pulmonary arterial pressure (LE = per session)
XN150	Therapy of coronavirus disease 2019 (COVID-19) with remdesivir [ATC: not available] (LE = per application)
XN160	Short-term circulatory support with micro-axial flow pump - percutaneous (LE = per session)
XN170	Minimally invasive implantation of self-expanding prostheses in the anal sphincter apparatus (LE = per session)

On June 22, 2022, the draft document "Changes and innovations in the 2023 LKF model" was published. The document summarizes the most significant changes and innovations in the LKF model for inpatient and outpatient care. In 2023, it is expected that the following five new provisional procedures will be introduced in the DRG system (in the 2023 DRG system).

Code	Name of procedure
XN190	Implantation of a fenestrated stent-graft - aortic arch (LE = per session)
XN200	Cardiac pacemaker implantation, His bundle pacing (LE = per session)
XN210	Implantation of a system for breathing-controlled stimulation of the hypoglossal nerve (LE = per session)
XN220	Percutaneous aspiration thrombectomy of the pulmonary artery (LE = per session)
XN230	Percutaneous aspiration thrombectomy heart/large veins with extracorporeal circulation (LE = per session)

The recent history of the framework is summarized below.

In 2019, nine provisional codes were present in the DRG catalogue. One procedure, "Implantation of a system for cardiac contractility modulation (reimbursement per session)," with the code XN020, was removed from the catalogue in 2020.

In 2020, no new provisional codes were added.

In 2021, three new provisional codes were included in the DRG catalogue:

- XN051 "Implantation of tricuspid valve clips – percutaneous";
- XN130 "Implantation of a leadless pacemaker - percutaneous";
- XN140 "Implantation of a system for telemedical monitoring of pulmonary arterial pressure".

Three new provisional codes were included in the DRG catalogue in 2022 (in the 2022 DRG system). It was the first time that the provisional procedure of drug administration was included in the DRG system:

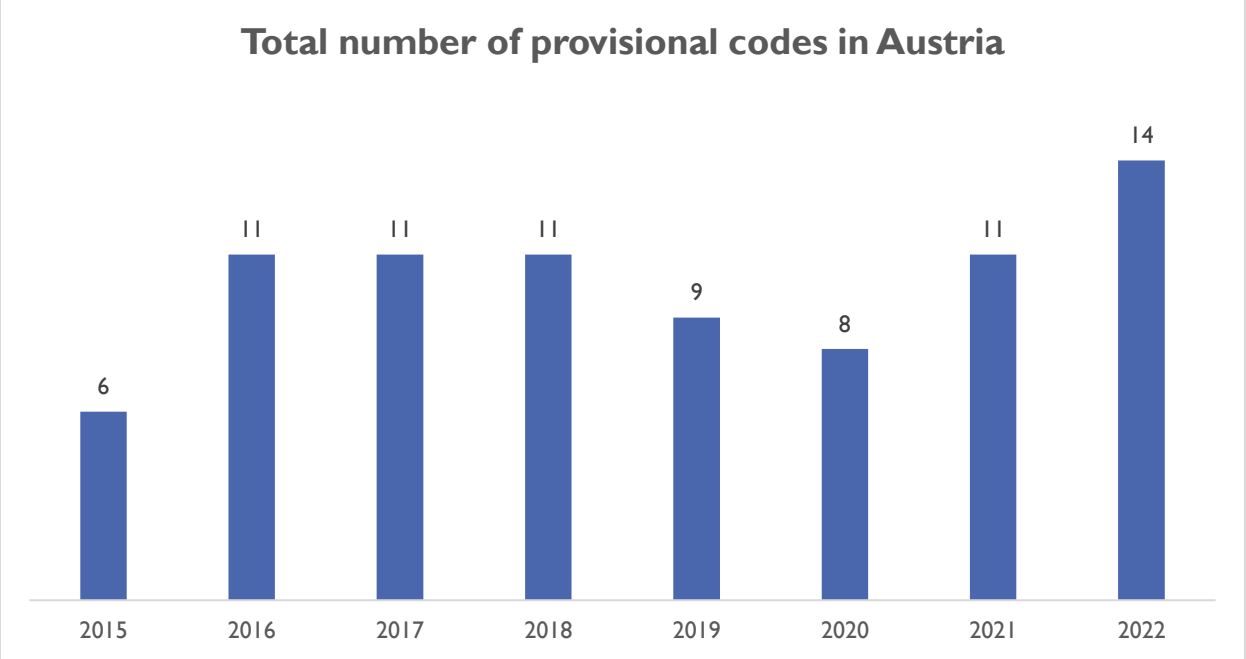
- XN150 "Therapy of coronavirus disease 2019 (COVID-19) with remdesivir [ATC: not available] (LE = per application)";
- XN160 "Short-term circulatory support with micro-axial flow pump - percutaneous (LE = per session)";
- XN170 "Minimally invasive implantation of self-expanding prostheses in the anal sphincter apparatus (LE = per session)".

In total, in the list of provisional codes as of July 1, 2022 (in the 2022 DRG system), eight procedures (57.1%) are from the cardiovascular area, three procedures (21.4%) – are from the neurovascular area, one procedure (7.1%) – is from the gastrointestinal area, and one procedure (7.1%) - from telemonitoring.

Number of provisional procedure codes in the past eight years

The figure below shows the total number (not newly added codes) of provisional codes between 2015 and 2022.

Provisional codes remain in the DRG system for several years. For example, out of eight procedures with provisional status in 2014, five were still included as provisional codes in 2019 and four - in the 2021 DRG system.



Reference

Web-link to the scheme.

BELGIUM: INTRODUCTION

Belgium has two active innovative payment schemes: so-called Restricted Clinical Application, which is focused on medical devices (used mostly in hospital settings, rarely in out-patient specialist settings), procedures, and (rarely) medical aids for use in community settings, and Temporary Reimbursement of Software Applications (mostly used in home-care settings).

BELGIUM: RESTRICTED CLINICAL APPLICATION FOR DEVICES

Title

Restricted Clinical Application for invasive medical devices and implants (in French: Application Clinique Limitée, ACL; in Flemish: Beperkte Klinische Toepassing, BKT).

Objective

Restricted Clinical Application scheme is intended to provide temporary (up to 3-5 years) reimbursement in a limited number of centres to generate additional evidence to inform further decision-making about permanent reimbursement for implantable and invasive medical devices in Belgium. This scheme can be classified as coverage with evidence development program.

Overview

Implantable and invasive medical devices require reimbursement registration in Belgium. Registration is performed by the National Institute for Health and Disability Insurance (Institut national d'assurance maladie invalidité, INAMI / Rijksinstituut voor ziekte- en invaliditeitsverzekering, RIZIV). The manufacturers make reimbursement applications. As a result of the application, materials (devices) can be added to the list of reimbursable devices, and a procedure code (if a new code is created) can be added to the INAMI/RIZIV Nomenclature. However, good clinical (RCT-level) and economic (cost-saving effect or high cost-effectiveness in Belgian settings) evidence is required to obtain registration.

When evidence is not sufficient to grant a permanent reimbursement, but innovation is promising, the Commission of Reimbursement of Implants and Invasive Medical Devices (CRIDMI / CTIIMH) can propose a temporary reimbursement for a limited period of time (3-5 years) in a limited number of hospitals to generate additional evidence to inform a final decision about reimbursement. The Commission defines the scope of the Restricted Clinical Application and invites hospitals to participate in the scheme. At the end of the coverage period, hospitals and a relevant professional organisation issue a joint report. On the basis of the report, the Commission decides on reimbursement of the device in Belgium (permanent reimbursement via the list of reimbursable medical devices).

The program was started in July 2014. Currently, technologies on the program belong to category G (the name of the category is "devices, which are reimbursed via ACL/BKT") of the list of reimbursable medical devices.

Care settings

In-patient, out-patient specialist settings, and community settings (home care). Previous decisions in the scheme mostly concerned hospital technologies, with the exception of continuous glucose monitoring technology.

Type of covered technologies

Mostly medical devices and procedures. Rarely, medical aids for use in community settings.

The only example of the inclusion of medical aid in the community settings in the scheme is the continuous glucose monitoring technology (2019).

Inclusion criteria

The scheme can be considered for an innovative technology when there is still uncertainty as to whether the technology provides an added value in relation to the other therapeutic options. The term 'uncertainty' is not defined, but it could include indications, clinical or health economic value.

Applicant

It is not possible to apply for the scheme. The manufacturer makes an application for inclusion in the reimbursement list of medical devices. The inclusion in the scheme is one of the outcomes of a reimbursement evaluation by INAMI/RIZIV.

Stakeholders involved

Stakeholder	Role
Commission of Reimbursement of Implants and Invasive Medical Devices	The decision to propose the Restricted Clinical Application scheme, determining conditions of the scheme

Role of the industry

The manufacturer makes an application for inclusion in the reimbursement list of medical devices. There is no direct role in relation to the Restricted Clinical Application scheme.

Clinical and economic requirements for the scheme

There are no clear requirements for the scheme. Technology should have established evidence, but the evidence must have some gaps that prevent it from obtaining permanent reimbursement. Typically, RCT-level evidence accompanied by cost-effectiveness and budget impact analysis is included in a submission dossier by the manufacturer for the final reimbursement application (not for the ACL/BKT scheme).

Statistics and trends about the use of the scheme

Since 2014 and until July 01, 2022, nine technologies were included in the Restricted Clinical Application scheme (Categories IG and IIG, link):

- Deep brain stimulation for refractory epilepsy (2015);
- Liver dialysis (2015);

- Deep brain stimulation for obsessive-compulsive disorder (2016);
- Deep brain stimulation for abnormal movements (2016);
- MitraClip for mitral insufficiency (2016);
- Ventricular assist devices (uni-, bi-ventricular) (2016);
- Watchman and Amplatzer for left appendage occlusion to prevent stroke (2017);
- Continuous glucose monitoring with implantable sensor (Eversense XL) for diabetes (2019);
- Dorsal root ganglion neurostimulation for complex regional pain syndrome (CRPS) of the lower limbs (2019).

Three technologies left the program and entered a regular reimbursement scheme: liver dialysis, deep brain stimulation for abnormal movements, and ventricular assist devices.

Therefore, six technologies are currently covered by the scheme.

Reference

No particular web-link to the scheme exists.

BELGIUM: TEMPORARY REIMBURSEMENT OF SOFTWARE APPLICATIONS

Title

Temporary reimbursement of software applications (level 3-) (in French: Remboursement temporaire des applications mobiles médicales, M3-; in Flemish: Tijdelijke vergoeding medische mobiele applicaties, M3-)

Objective

Temporary reimbursement (level 3- of the Belgian validation pyramid) is dedicated to software applications with the involvement of patients (including health apps, digital platforms, and remote monitoring solutions) that achieved certain quality and safety requirements (levels 1 and 2) but have not sufficient evidence of social-economic added value. Once the software application from 3- has proven its added value, it can reach level 3+ and be reimbursed on a regular basis. This scheme can be classified as coverage with evidence development.

Overview

The development of a reimbursement framework for software applications was initiated in 2016 as a pilot by the National Institute for Health and Disability Insurance (NIHDI / INAMI-RIZIV) in collaboration with FPS Public Health, the Federal Agency for Medicines and Health Products (FAMHP / AFMPS-FAGG).

In 2020, the administrative framework for software applications became permanent at the mHealthBelgium platform, which is led by the Belgian Federation of the medical technology industry (beMedTech) and the Belgian Federation of Technology Companies (Agoria) in cooperation with the national authorities (INAMI/RIZIV, FAMHP, and the eHealth platform).

The central part of the framework is the so-called "validation pyramid" for software applications, which consists of three levels.

Level 1 determines the basic criteria for a software application: CE certification as a medical device, notification of the software application to the FAMHP, and compliance with the EU General Data Protection Regulation (GDPR).

Level 2 concerns interoperability and connectivity with the basic services of the eHealth platform. Software applications must meet all level 1 criteria and all imposed criteria regarding authentication, security, and the use of local e-health services utilising standardized tests.

To reach level 2 of the validation pyramid, the software application must confirm the interoperability and connectivity to the basic services of the eHealth platform. The developer of the software application contacts the eHealth platform to be assessed by an independent test organisation (the application process is described here). The assessment is based on six criteria described here.

Software applications that achieved levels 1 and 2 of this pyramid can possibly reach level 3 and be reimbursed within the context of a specific care process. This level is sub-divided into two sub-levels:

- Level 3- ("light"), when the software application has not (yet) proven social-economic (sufficiently) evidence and is still collecting data about social-economic added value and is reimbursed on a temporary basis;
- Level 3+ ("plus"), when a software application has sufficient evidence of social-economic benefits and can be reimbursed on a permanent basis.

Software applications are never reimbursed per se but only as part of the relevant care process in which the role of the software application is defined. There are two steps to obtain reimbursement (level 3+ or 3-, depending on the evidence available):

1. Manufacturer companies/distributors of software applications submit a notification form of the possibility of integrating a software application into existing, modified, or new care processes to INAMI/RIZIV. If the care process is not defined, its creation is triggered by the application. In the notification form, the applicant describes the added value for the patient, the care provider, and the society, describes the place of the software application in the care process, describes the target group, and provides clinical and health-economic evidence. The budget impact should be calculated based on the expected number of users and the proposed new or modified care process. The decision-making process includes the following:
    - INAMI/RIZIV sets up a specific working group made up of independent and experienced experts in the care process concerned, representatives of competent care providers, insurers and patients, representatives of employer's and worker's organisations;
    - The working group reviews the application based on the clinical evidence, the feasibility of integration into the care process, improvement and/or possible addition to current practice (added value), and the budget impact. This may take up to six months;
    - The working group submits an opinion to the INAMI/RIZIV Insurance Committee. In case of positive opinion, the group proposes how to integrate the software application into the

reimbursement system and present responsibilities (technical advisers, convention commissions, etc.);
- Based on the working group's opinion, INAMI/RIZIV Insurance Committee decides whether or not to integrate the software application into the care process and the reimbursement system;
- If there is no relevant care process that considers the use of the software application, a dedicated working group set by INAMI/RIZIV needs to establish a new care process that defines the role of the software application;
- If there is insufficient evidence of social and economic added value, INAMI/RIZIV Insurance Committee may decide on temporary reimbursement for the software application and launch a clinical study (level 3-). The duration of the study is not clearly defined. After completion of the study, INAMI/RIZIV Insurance Committee will re-evaluate the software application to decide on the inclusion in regular reimbursement.

2. When the care process which concerns the use of a software application already exists/is established by INAMI/RIZIV, the software application must be introduced to the Nominative list with reimbursable software application for this care process. The manufacturer must submit another request form to include the software application in the Nominative list of software applications eligible for reimbursement for this care process. The application form for inclusion in the Nominative list is available here. The procedure codes for services performed using a software application, with the reimbursement tariffs, are presented in the same excel file, which contains the Nominative list of software applications.

Care settings

Most medical software technologies are used in community settings (home care).

However, some can be used in in-patient and out-patient specialist settings. The only available decision in the scheme relates to a software application for rehabilitation in hip or knee replacement (MoveUP Coach), which is used before, during, and after hospitalisation.

Type of covered technologies

CE-marked medical devices only. Medical software that allows the patient to share health-related information with a healthcare professional. These can be health apps, digital platforms, or remote monitoring solutions.

Inclusion criteria

To be eligible to apply for level 3, a software application with a medical purpose should meet the following criteria:

- CE marking as a medical device;
- Achieved level 2 of the validation pyramid;

- Allows the patient to share health information from their own environment (with or without sensors) with a healthcare provider;
- Allows a healthcare professional to diagnose, apply therapy, or monitor a patient, all from a distance, via a medical device made for use by the patient in their own environment.

Applicant

Manufacturers/distributors of medical software.

Stakeholders involved

Stakeholder	Role
National Institute for Health and Disability Insurance (NIHDI / INAMI/RIZIV)	Responsible for levels 3+ and 3- of the validation pyramid INAMI/RIZIV Insurance Committee decides on reimbursement (temporary level 3- or regular level 3+)
Specific working groups of INAMI/RIZIV	For each application for integration of a software application into the care process, INAMI/RIZIV sets up a specific working group to review the application and provide an opinion to INAMI/RIZIV Insurance Committee
eHealth Platform	The eHealth Platform is a federal government institution providing a well-organized, mutual electronic service and exchange of data between all healthcare stakeholders Responsible for level 2 of the validation pyramid
Federal Agency for Medicines and Health Products (FAMHP / AFMPS-FAGG)	FAMHP is the competent authority for all areas related to the quality, safety, and efficacy of medicines and health products, including medical devices Responsible for level 1 of the validation pyramid
Belgian Federation of the medical technology industry (beMedTech)	Manages mHealthBelgium platform
Belgian Federation of Technology Companies (Agoria)	Manages mHealthBelgium platform

Role of the industry

The manufacturer company/distributor applies to INAMI/RIZIV about the possible integration of the software application into the new, modified, or existing care process, once their software application has achieved levels 1 and 2. After a positive decision from INAMI/RIZIV, and when the specific care process exists/is established, the manufacturer/distributor submits another application to include the health software application in the Nominative list for this care process.

Industry federations (beMedTech, Agoria) manage mHealthBelgium platform.

Clinical and economic requirements for the scheme

The inclusion criteria (provided in the inclusion criteria section above) should be met. Furthermore, manufacturers/distributors of software applications submit a notification form to integrate their product into existing or new care processes, which should include the following data:

- Description of the software application: general (e.g., self-monitoring, telemonitoring, diagnostic tool, etc.), general place in the care process, functioning, data collection and exchange, the technology/platforms used, the minimum conditions of use, accessibility of these platforms;
- Prices and costs: an overview of the costs associated with the existing, modified, or new care process; price justification (cost structure, planned volumes, staff costs, etc.); if the software application is already reimbursed in other countries, in what form, and for what amount; documentation (e.g., brochures, manuals, CE marking, report on interoperability (level 2), confirmation of notification to the FAMHP);
- Target population: the patients and/or caregivers who are authorised to use this software application. The expected annual number of users in Belgium is important for the correct estimation of the budget impact;
- Care process: detailed description of the current care process without using the software application and new/updated care process with the use of the software application;
- Scientific analysis: the added value of the software application compared to existing alternatives. The following should be mentioned (based on RCTs, international guidelines recommending the technology, expert opinions, etc.):
    - Evidence of efficacy, improvement in the quality of care, and the patient's quality of life. At least one comparative study;
    - Patient outcomes and experiences (PROMs, PREMs). Clinical validation (therapeutic added value);
    - Ongoing and planned studies;
- The clinical utility should be quantified based on the results of the studies. This quantification is important for the budgetary impact analysis, the health economic, and the transferability;
- The budget impact is calculated based on the expected number of users and the proposed new or modified care process;
- Transferability – impact on other budgets of compulsory healthcare insurance should be discussed, for example:
    - Reduction in the number of consultations;
    - Reduction in the number of diagnostic tests or therapeutic services;

  These calculations do not include costs and savings to society that are not directly related to health care.

- Cost efficiency: the expected impact on the patient's quality of life and the health economics (cost-benefit) analysis of the new care process;

The specific working group set up by INAMI/RIZIV will review the notification and prepare an opinion for the INAMI/RIZIV Insurance Committee, considering the following key data:

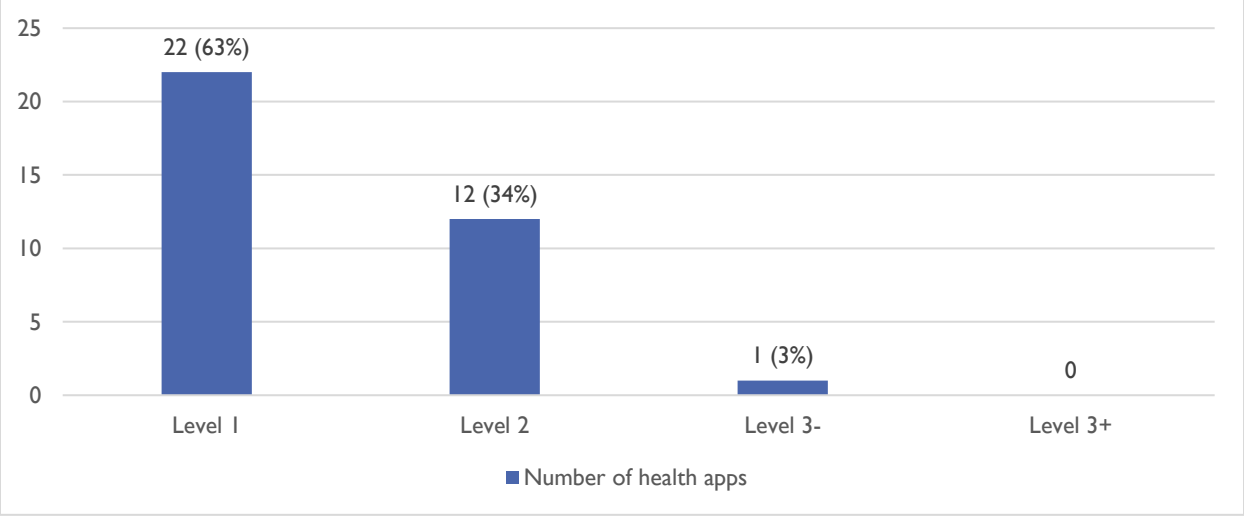
- Clinical evidence;
- Feasibility of integration into the care process;
- Improvement and/or possible addition to current practice (added value);
- The budget impact.

The application for the registration of a software application on the Nominative list within a specific care process contains process-specific requirements for the technology. An example of an application form within the care process for rehabilitation after a knee or hip prosthesis can be seen here.

Statistics and trends about the use of the scheme

As of July 1, 2022, a total of 35 software applications are presented on the mHealthBelgium platform (link). Only one software application (moveUP Coach) obtained temporary reimbursement (achieved level 3- of the validation pyramid). No software applications obtained regular reimbursement (achieved level 3+ of the validation pyramid).

The figure below represents a distribution of software applications at each level of the validation pyramid as of July 1, 2022.



As explained above, software applications must be included by INAMI/RIZIV in care processes in order to be reimbursed. As of July 01, 2022, there is only one care process in which software applications can be reimbursed, and it is the process of rehabilitation after knee or hip prosthesis. The only app reimbursed (at level 3) is part of this care process (moveUP app; level 3-).

In the past, only one more care process existed and was eligible for reimbursement: remote monitoring of COVID-19 patients at home. However, this framework was discontinued on June 30, 2022. No digital technologies, which could have become a part of this care process, received reimbursement (achieved level 3 of the validation pyramid).

Furthermore, two more health apps have already received a positive opinion (one for sleep therapy and another in the oncology field) (reference). However, INAMI/RIZIV is still in the process of revising the care processes in these two areas, which is necessary to define the role of health apps in the care pathway. Thus, these software applications did not yet obtain reimbursement (achieve level 3 of the validation pyramid).

As of July 01, 2022, no care processes in which health apps are permanently reimbursed exist.

Reference

Web-link to the scheme (INAMI/RIZIV).

Web-link to the scheme (mHealthBelgium platform).

ENGLAND: INTRODUCTION

England has three active innovative payment schemes:

- Artificial Intelligence in Health & Care Award England (Phase 4), which focuses on AI technologies and software, both as support tools for physicians and patient use at home;
- Innovation competition at the NHS Cancer Programme is focused on technologies that help fight cancer, including laboratory tests, digital technologies (AI-based platforms for use by physicians, management systems), and care pathway optimisation;
- Medtech Funding Mandate, which can cover any type of technology, including medical devices, in-vitro diagnostic tests, diagnostic technologies, and digital health technologies. The focus of the Mandate are technologies delivered in any type of setting.

ENGLAND: ARTIFICIAL INTELLIGENCE IN HEALTH AND CARE AWARD

Title

Artificial Intelligence in Health and Care Award (AI Award) (Phase 4)

Objective

AI Award is a competitive process to accelerate the testing, evaluation, and adoption of the most promising AI technologies that meet the strategic aims set out in the NHS Long Term Plan. Awarded products receive funding and support depending on their development stage: from Phase I for the products/concepts at the initial stage to Phase 4 for real-world testing and adoption of products with market authorisation.

The objective of Phase 4 is to demonstrate the clinical and economic impact of promising products in the NHS and/or social care setting to inform reimbursement and procurement decisions and facilitate systems adoption. Phase 4 program can be considered as coverage with evidence development program.

Overview

AI Award was launched in 2020 with £140 million funding from the government. AI Award is run by the NHS Accelerated Access Collaborative (AAC) in partnership with NHS AI Lab (part of NHSX – now part of the NHS Transformation Directorate) and the National Institute for Health and Care Research (NIHR).

AI Award supports innovators and technologies across the spectrum of development: from concept to initial NHS adoption and testing within clinical pathways. Products can apply for funding within one of the following four Phases:

- Phase 1: Product and clinical feasibility – is intended to show the technical and clinical feasibility of the proposed concept, product, or service;
- Phase 2: Product development and clinical evaluation – is intended to develop and evaluate prototypes of demonstration units and generate early clinical safety and efficacy data;
- Phase 3: Real-world testing – is intended to support the first real-world testing in health and social care settings to develop further evidence of efficacy and preliminary proof of effectiveness, including evidence for routes to implementation to enable more rapid adoption;
- Phase 4: Initial health system adoption – is intended to identify medium-stage AI technologies with market authorisation but insufficient evidence to merit large-scale commissioning or deployment. Grants are uncapped, per technology, typically for 12-36 months.

Calls for applications for the AI Award run through open competition Rounds. As of July 01, 2022, three calls were completed, and no information is available regarding further calls.

- In 2020, Round 1 awarded a total of 42 technologies (10 of them in Phase 4) with an overall funding amount of over £50 million;
- In 2021, Round 2 awarded a total of 38 technologies (5 of them in Phase 4) with an overall funding amount of over £36 million;
- The Round 3 competition application period was open from June to September 2021. Winners were expected to be announced in spring 2022. However, they are not announced as of October 17, 2022.

All applications must be made through the online application portal. Guidance on completing a stage 1 application form is available here.

For Phase 4 technologies, grants per technology are uncapped but typically range £1-7 million. Fundable activities include, but are not limited to:

- Activities associated with the design and delivery of evaluations of AI solutions across multiple health and social care settings, including any trial methodology aimed at demonstrating real-world evidence of the clinical or economic utility of the product with respect to its real-life implementation and use:
    - Prospective studies that evaluate the ability to estimate outcomes where there is typically no suspected risk;
    - Qualitative research on setting-specific aspects regarding scaling the technology, including readiness for cultural change, clinical adaptation (IT, information governance, and data infrastructure), and long-term adherence to the technology;
- Small changes to the technology that might be needed for its optimisation during the lifetime of the project, e.g., any changes deemed required for the end user acceptance as part of this evaluation but not requiring any further regulatory approvals;
- Activities associated with the data analysis, management, and governance of real-world evaluations;
- Development of research protocol and ethics;
- Development of rich and in-depth case studies conducted in multiple NHS sites that may serve as adoption exemplars and reference sites;
- Costs associated with implementation research, including the design of the implementation strategy, clinical pathway analysis, and sustainability evaluation;
- Training associated with the implementation of new technology, including the development of training resources and materials;
- Health economic analyses, including cost-effectiveness, cost-utility, or cost-benefit analyses to determine any cash savings or cash releases;
- Activities in relation to business development, market analysis, and development of a case for adoption;
- Activities associated with the dissemination of outputs;

- Research to support patient and public engagement or involvement.

Technologies awarded in Phase 4 are then implemented in the NHS organisations (mapped here).

In 2021, the AAC and NHS England began working with the Round 1 winners to better understand the barriers and enablers of successful AI development, implementation, and adoption in the UK. AAC commissioned independent evaluations for all our Phase 4 Award winners. The results will be published upon completion. These evaluations fill key evidence gaps for relevant published evidence standards frameworks and accelerate local and national adoption. Evaluations will focus on accuracy, safety, effectiveness, value, fit with the site, implementation, feasibility of scale-up, and sustainability of scale-up.

The AAC will also continue to work with regulatory bodies and industry partners to develop and identify frameworks for the fast and safe deployment of AI health and care technologies into the NHS.

Care settings

In-patient, out-patient specialist settings, primary care, and community settings (home care).

Type of covered technologies

AI-based medical technologies (CE or UK Conformity Assessed (UKCA) approved).

Inclusion criteria

National Institute for Health and Care Research defines inclusion criteria here. The application process is run in two stages. Stage 1 applications must meet all phase-appropriate entry/exit points, award specifications, and funding prerequisites to be considered for review. Applications that do not meet these requirements will be rejected at this stage. Eligible applications are reviewed against AI Award assessment criteria. Selected stage 1 applications are then shortlisted and invited to submit a Stage 2 application.

The following entry point (the minimum eligibility requirement) should be met for the Phase 4 Stage 1 applications:

- Real-world efficacy was demonstrated, with prospective evidence generated from at least two implementation sites;
- CE/UKCA marked;
- Regulatory approvals in place;
- Market authorised;
- Robust health economics (including cost-effectiveness or budget impact analysis).

Phase 4 exit points (results of the scheme) are feasibility for large-scale deployment, real-world efficacy demonstrated in multiple sites, and real-world health economic evidence.

The Phase 4 award specification includes the following requirements:

- Development stage: initial health system adoption;
- Location of lead organisation: worldwide (applicant should have a UK registered office or a UK health or social care organisation as a co-lead);
- Location of partners: can be outside the UK;
- Collaborators: three or more NHS or social care adoption sites;
- Funding limit: Uncapped but typically range £1-7 million;
- Project duration: 12-36 months.

The following funding prerequisites apply to all applications and are considered by the funding panel:

- The AI technology utilises artificial intelligence to address a need or problem facing the NHS in a priority area, which may include those identified in the NHS Long-Term Plan;
- The AI technology has the potential for routine use in health and/or social care in England, as demonstrated by a clear route to market and the ability to scale up;
- Sufficient evidence that the AI solution can meet at least one of the following criteria at a level appropriate to the stage of development:
    - Improvement in patient and/or service user outcomes or experience;
    - Improvement in operational efficiency.
- A commitment to involving members of the public and patients in the design and management of the research, evaluation, or study;
- Ability to demonstrate rights to access and use the data as required to deliver the proposed project, including but not limited to any clinical/patient data needed to train or validate any models or algorithms;
- Commitment to relevant standards: Where appropriate, these will include the AI Code of Conduct for data-driven health and care technology (for artificial intelligence systems used by the NHS), the NICE Evidence Standards Framework for digital health technologies, the NHS Digital Standards for commissioning or developing Personal Health Records;
- Ability to demonstrate interoperability with existing NHS systems or a commitment to work towards and fund any relevant product development required to achieve interoperability. This includes ensuring the AI solution is vendor-neutral;
- Relevant approvals in place or working towards relevant approvals:
    - Regulatory, intellectual property protection, ethical framework, or any other relevant approvals;
    - Conformité Européene (European Conformity; CE) or UK Conformity Assessed (UKCA) marking and/or market approvals;
    - Demonstrate Information Governance (IG) compliance in line with General Data Protection Regulation (GDPR);
    - Not subject to any Medicines and Healthcare products Regulatory Agency (MHRA) safety alerts.

Stage 1 applications are assessed against the following AI Award criteria:

- NHS unmet needs and market pain. How well does the AI solution support health and care priorities and align with wider government strategies?
- The benefit to patients, the NHS, social care, and the wider population. What is the expected improvement in health and care outcomes, health and care inequalities, operational efficiency, patient/service user experience and/or safety, and quality of care?
- The proposed technology and level of innovation. How innovative is the proposed AI solution, and how significant is the competitive advantage that this technology affords?
- Quality of the work plan. How appropriate is the work plan, and are the risks and mitigation strategies clearly articulated?
- Intellectual Property (IP), commercialisation, and NHS adoption strategy. Based on the Phase of development, how appropriate and sustainable are the plans described?
- Patient and public involvement. Is the involvement of patients, the public, and end-users appropriate and relevant?
- Strength of the project team. To what extent does the team have the right skills and experience to deliver the project, and if applicable, have they demonstrated sufficient engagement in deployment sites?
- Value for money. Is the overall budget realistic and justified in terms of the aims and methods proposed? Does the funding amount present value for money with regard to potential impact?

Applicant

Applications can be submitted by a small-to-medium-sized enterprise (comment: not defined in the document, but the UK government typically defines it as any organisation that has fewer than 250 employees and a turnover of less than €50 million or a balance sheet total of less than €43 million; reference), large enterprises, an NHS or social care organisation or service provider, a higher education institution, a charity, or a local authority.

Stakeholders involved

Stakeholder	Role
NHS Accelerated Access Collaborative (AAC)	Run AI Award in partnership with NIHR and NHS AI Lab The AAC Delivery team works with NHS sites to support the adoption of Phase 4 technologies, to stress test and evaluate the AI technology within routine clinical or operational pathways to determine efficacy or accuracy, and clinical and economic impact
NHS AI Lab (part of NHS Transformation Directorate)	Run AI Award in partnership with NIHR and NHS ACC Funding of AI Award
National Institute for Health and Care Research (NIHR)	Run AI Award in partnership with NHS AAC and NHS AI Lab Responsible for technical support, e.g., the application process, calls for competitions, guidance, and other materials for applicants

Role of the industry

Small-to-medium-sized enterprises and large enterprises (only for Phases 3 and 4) can submit applications for the scheme.

Clinical and economic requirements for the scheme

Technology must meet all phase-appropriate entry/exit points, award specifications, and funding prerequisites, as described above in the inclusion criteria section. Eligible applications are reviewed against AI Award assessment criteria.

The minimum requirement for Phase 4 is CE/UKCA-marked AI products with clearly identified NHS and/or social care benefits derived from a robust health economic assessment or NICE appraisal.

One of the inclusion criteria for the scheme is that real-world efficacy must be demonstrated with prospective evidence from at least two implementation sites.

Statistics and trends about the use of the scheme

Round 1 winners were announced on September 08, 2020. Over 530 applications were received, and a total of 42 awards were made, ten of which were in Phase 4 (link):

Technology	Link	Summary
Veye (Aidence)	Link	AI platform to optimise oncology pathways, which can be integrated into existing software systems
e-Stroke Suite (Brainomix)	Link	AI-based tool to interpret acute stroke brain scans. It also provides a platform for doctors to share information between hospitals in real-time
RITA: Referral Intelligence and Triage Automation (Deloitte)	Link	AI solution to automate the triage of GP referrals – assessing the urgency and next step for the referral and sending through directly to the next step in the process
Smartphone albuminuria self-testing (Healthy.io)	Link	A home test kit and mobile app for self-test at home with clinical grade results
DrDoctor (ICNH)	Link	AI-based patient engagement platform that supports communications, appointment management, and remote care
Zio Service (iRhythm)	Link	A complete and clinically proven ambulatory ECG monitoring service utilising powerful AI-led processing and analysis to support clinical workflows and improve the diagnostic yield and timeliness of cardiac monitoring
Mia Mammography Intelligent Assessment (Kheiron Medical Technologies)	Link	Deep learning software that has been developed to solve critical challenges in the NHS Breast Screening Programme (NHSBSP), including reducing missed cancers, tackling the escalating shortage of radiologists, and improving delays that put women's lives at risk
DLCExpert (Mirada Medical)	Link	Uses AI-based software to automate the time-consuming and skill-intensive task of outlining (or "contouring") healthy organs on medical images for radiotherapy planning so that they are not irradiated during treatment

Technology	Link	Summary
Automated diabetic retinal image analysis software (Optos PLC)	Link	Uses a machine learning algorithm to analyze images of the back of the eye for the presence or severity of any diabetic retinopathy and then advises if referral to an eye care specialist is needed (based on the local clinical pathway)
EchoGo Pro (Ultromics)	Link	A fully automated and scalable application for quantification and interpretation of stress echocardiograms that autonomously processes real-world echocardiographic image studies to predict prognostically significant cardiac disease

Round 2 winners were announced in June 2021. Over 350 applications were received, and a total of 38 awards were made, five of which were in Phase 4 (link):

Technology	Link	Summary
DERM (Skin Analytics Ltd)	Link	Analyses skin lesion images distinguishing between cancerous, pre-cancerous, and benign lesions
eHub (eConsult Health Ltd)	Link	Intelligently triage and automate general practices (GP) e-consultation requests
Chest X-ray analysis (Behold.AI Technologies Ltd)	Link	AI algorithm to fast-track the diagnosis of suspected lung cancer patients, offering them same-day CT scans; Patients with no abnormalities at chest X-rays will receive a diagnostic report in seconds
Paige Prostate cancer diagnostic system (University of Oxford)	Link	Interpretation of pathology sample images
Bone Health Solutions (Zebra Medical Vision)	-	Analyses CT scan to catch undiagnosed spinal fractures, which can be a marker for osteoporosis

Reference

Web-link to the scheme.

ENGLAND: INNOVATION CALL AT THE NHS CANCER PROGRAMME

Title

Innovation Open Call at the NHS Cancer Programme

Objective

Innovation Open Call at the NHS Cancer Programme is an annual competition for funding to implement late-stage development solutions that improve the early detection and diagnosis of cancer. The awarded innovations are tested and evaluated in real-world settings, so those that will make the most significant difference can be rapidly implemented across the NHS. The competition is open to all types of innovations, including medical devices, in-vitro diagnostics, digital health solutions, behavioural interventions, software, artificial intelligence, or new models of care. The scheme can be classified as coverage with evidence development program.

Overview

The NHS Cancer Programme at NHS England and NHS Improvement (NHSEI) leads the delivery of the NHS Long Term Plan ambitions for cancer. An annual Innovation Open Call at NHS Cancer Programme was launched in 2021 to accelerate innovations or new approaches that will increase the proportion of cancers diagnosed at stage one or two.

The call aims to support the implementation of these innovations into front-line clinical settings by shortening the gap between the evidence collated from traditional safety/efficacy clinical trials typically required for regulatory approvals (CE marking or equivalent) and the evidence required by commissioners to make purchasing decisions.

SBRI (Small Business Research Initiative) Healthcare runs the Innovation Open Call. SBRI Healthcare is an initiative of NHS England supported by the Academic Health Science Networks (AHSNs). The first competition was completed in 2021, and awarded projects were announced in February 2022. The second competition call closed in May 2022, and awarded projects are expected to be announced in October 2022 (not yet announced as of October 17, 2022).

Successful applicants are selected by an open competition process and retain the intellectual property rights (IPR) generated from the project, with certain rights of use retained by the NHS.

Awarded projects are 100% funded for up to £4 million (net) for a maximum of 18 months in the first instance. Project activities and associated costs, which are covered by the funding, are:

- Cost to supply the innovation;
- Training costs;
- Clinical staff time to administer the innovation;
- Management costs for hospital trust to implement the innovation;

- Other implementation costs;
- Independent evaluation costs, including data collection and analysis, impact on care pathway, clinician and patient acceptability, health economics
- Minor technology development work (e.g., minor adaptations for user acceptability, system integration, etc.).

Eligible costs include salary, recruitment, consumables, overhead, estate, and contractor costs.

After the awarded projects are completed, the technologies that showed the most significant benefits will be rapidly implemented across the NHS.

Care settings

In-patient, out-patient specialist settings, primary care, and community settings (home care).

Type of covered technologies

Rarely, medical procedures. Typically, medical devices, in-vitro diagnostics, and digital health technologies.

The only example of the inclusion of medical procedures in the scheme is whole body MRI for inherited cancer early diagnosis.

Inclusion criteria

The call is open to any innovation at a late stage of development with proven efficacy and clinical effectiveness which meets the following requirements: CE mark or equivalent regulatory approval obtained (if required for the innovation), and /or it is in use in at least one NHS Trust in standard routine care (non-research).

Applicants should address the following points in their proposals:

- The likely impact of the proposed innovation compared to the current patient pathway, and what is the potential impact on stage distribution and survival based on current data;
- The impact of the proposed solution on cancer services and how will the system needs to be changed (including people, processes, and culture) to deliver system-wide benefits;
- Ensure that the innovation will be acceptable to patients (and their families and wider support network) and clinician groups/health care professionals. How have these groups been involved in the design and development of the innovation;
- Ensure that the innovation is affordable to the NHS and wider systems such as ICSs both immediately and throughout the sustained life of the product. What health economics and impact evidence will be required by the NHS and wider system before the technology can be fully adopted;
- For digital innovations, the NICE Digital Health Technology Framework and the NHSX guidelines for designing and building products and services should be considered.

Applicant

The competition is open to single organisations (contracts are executed with individual legal entities) based in the UK or EU from the private, public, and third sectors, including companies (large corporates and small and medium enterprises), charities, universities, and NHS Foundation Trusts, as long as a strong implementation and commercial strategy is provided. Organisations based outside the UK or EU with innovations in the remit for this call can apply as subcontractors of a lead UK/EU-based organisation or via a UK or EU subsidiary.

All proposals are expected to have partnerships with at least one NHS organisation, if they are not already led by one, and engage with appropriate suppliers to cover the expertise required for the successful delivery of the project. Engagement with Cancer Alliances and AHSNs is particularly encouraged.

All applications should be made using the online portal, which can be accessed through the Research Management System.

Stakeholders involved

Stakeholder	Role
NHS England and NHS Improvement (NHSEI)	NHS Cancer Programme is funding the Innovation Open Call NHS Accelerated Access Collaborative (AAC) responsible for coordination between stakeholders
SBRI Healthcare	Runs competition calls, provide all supporting information and documents
Academic Health Science Networks (AHSNs)	Support SBRI Healthcare, collaborate with companies

Role of the industry

Companies (large corporates and small and medium enterprises) can submit applications for this program.

Clinical and economic requirements for the scheme

To be considered within the competition, late-stage technologies should have proven efficacy and clinical effectiveness and be ready for real-world testing and roll-out.

There is no particular role for published real-world evidence as the requirement for enrollment in the scheme.

However, the primary aim of the evaluation of awarded technologies is to demonstrate the impact of the innovation in a real-world setting through cost-effectiveness and health outcomes. The evaluation

may also consider the barriers and enablers to implementation, as well as the resources required for large-scale commissioning.

Statistics and trends about the use of the scheme

The first Innovation Open Call was launched in March 2021. A total of 55 applications were received. Eight projects (14%) were awarded in February 2022, sharing over £9 million (link).

Title of the project	Link	Summary
Improving NHS Urgent Referral Pathways using an Artificial Intelligence driven, affordable blood test, PinPoint Data Science Limited	Link	PinPoint is a new type of blood test designed to help GPs to determine the chance that a patient has cancer
Telescopic referrals to increase the efficiency of the head and neck two-week wait cancer pathway, Endoscope-i Ltd	Link	Endoscope-i is an endoscope with a recording device that enables doctors to capture high-definition images from suspected head and neck cancer patients
Scaling and evaluating a clinical pathway management system to optimise referral, triage, and diagnostic workflow, Open Medical Ltd	Link	Pathpoint eDerma is a clinical pathway management system to help diagnose skin cancer and rapidly exclude patients without cancer from the diagnostic pathway. Dermatoscopy images of the suspected skin cancer can be reviewed and triaged immediately using smartphones and tablets
Whole body MRI for inherited cancer early diagnosis (SIGNIFIED), the Royal Marsden NHS Foundation Trust	Link	Implementing annual whole-body MRI scans in patients with Li-Fraumeni syndrome
Artificial Intelligence (AI) assisted Chest X-ray triage, Qure.ai Technologies Limited	Link	AI algorithm interprets patient chest X-rays and identifies abnormalities that could indicate lung cancer
MSI-Plus assay for Lynch Syndrome screening and therapeutic targeting, the Newcastle upon Tyne Hospitals NHS Foundation Trust, and Newcastle University	Link Link	The MSI-Plus assay allows simultaneous testing for markers to diagnose Lynch syndrome and other markers important for cancer treatment
Applying a cancer care toolkit for improving time from diagnosis to treatment, Orion Medtech Ltd CIC	No data	A digital platform to support the management of patients diagnosed with brain cancer. The platform allows data to be shared between hospital trusts and will enable diagnostic tests, clinic reviews, and discussions between specialists to happen in parallel
Liquid biopsies for faster diagnosis of Pancreatic and Biliary Tract Cancers, the Royal Marsden NHS Foundation Trust	Link	New diagnostic blood tests to prevent some patients from invasive tests and provide them with a faster and safer diagnosis

The second Innovation Open Call closed in May 2022. The awarded projects are expected to be announced in October 2022.

Reference

Web-link to the scheme.

ENGLAND: MEDTECH FUNDING MANDATE

Title

MedTech Funding Mandate (MTFM)

Objective

MedTech Funding Mandate (MTFM) supports the use of NICE-approved, clinically effective, and cost-saving medical devices, diagnostics, and digital technologies, making it mandatory for commissioners and providers to implement them.

Although the Mandate itself does not include dedicated funding, commissioners (local or NHS England) are mandated to reimburse providers for the use of MTFM technologies in addition to the national tariff. The scheme can be classified as an unconditional innovation payment scheme.

Overview

NHS England and NHS Improvement (NHSEI) decided to initiate the MTFM in 2019, to support getting innovative medical devices, diagnostics, and digital products to patients faster. However, the MTFM policy launch was delayed due to the COVID-19 pandemic.

In January 2021, the first MTFM policy for 2021/22 was published by the NHS Accelerated Access Collaborative (AAC), and the scheme became fully operational in April 2021. In March 2022, AAC published the 2022/23 MTFM policy.

The scheme is updated annually. The key characteristics of the process include the following:

- NHS England's delegated team (Innovation, Research and Life Sciences team, IRLS), jointly with NICE, reviews potential candidates for inclusion on the basis of released medical technologies guidance (MTG) and diagnostics guidance (DG) by NICE throughout the year until June 30;
- A list of technologies that meet the MTFM criteria is published on the AAC webpage (usually in the same-year autumn), with accompanying support to providers to adopt these technologies as soon as possible;
- The technologies already covered by the MTFM are reviewed annually to decide if any should be removed, including those for which NICE guidance has been significantly updated;
- If any technologies are withdrawn, this is announced before the policy publication;
- The MTFM policy is published annually by April 01 of the next year;
- The technologies covered by the MTFM are also included in annual publications of the National Tariff Payment System (NTPS) and NHS Standard Contract.

MTFM technologies are listed in the National Tariff Payment System's Annex A (Innovative products list, tab 14c). Items on this list are excluded from national tariffs and reimbursed by respective

commissioners (local commissioners or by NHS England). Reimbursement amounts for each technology or procedure are not provided in the MTFM or the National Tariff.

The payment model in England is changing following the NHS Long Term Plan and response to the COVID-19 crisis. From 2021/22, the aligned payment and incentive (API) approach (a combination of a fixed component and activity/quality-based funding) became the central part of the National Tariff. In 2021/22, for any technologies supported by the MTFM, the activity and cost were agreed upon between providers and commissioners and added to the fixed payment (meaning that there was no explicit additional reimbursement and technologies supported with MTFM were covered within a fixed budget, received by hospitals).

In 2022/23, MTFM technologies are excluded from the fixed element of the API approach and reimbursed by local NHS commissioners on a "pass-through" or cost and volume approach. However, the cost of implementation is included in the fixed element of API. Spectra Optia, for the treatment of sickle cell patients, is the only technology which is part of the MTFM that is funded nationally by NHS England.

Technologies in the MTFM can be procured through the relevant NHS Supply Chain framework from April 01, 2021 (except Spectra Optia).

Care settings

In-patient, out-patient specialist settings, and community settings (home care). Previous decisions in the scheme mostly concerned technologies used in hospital and out-patient specialist settings, with the exception of Thopaz+, which can be used by patients at home.

Type of covered technologies

Medical devices, in-vitro diagnostics, and digital health technologies.

Inclusion criteria

In 2021/22, the original MTFM supported devices, diagnostics, or digital products that:

- Are effective: demonstrated through positive NICE medical technologies guidance (MTG) and diagnostics guidance (DG);
- Deliver material savings to the NHS: the benefits of the innovation are over £1 million over five years for the population of England;
- Are cost-saving in-year: NICE modeling demonstrates a net saving in the first 12 months of implementing the technology;
- Are affordable to the NHS: the budget impact should not exceed £20 million in any of the first three years**.**

To ensure that the first MTFM policy does not burden providers and commissioners, it was launched with a few products that met the criteria above and were previously supported through the

Innovation and Technology Payment (ITP) program. For the subsequent MTFM policies, the previous inclusion in ITP program is no longer necessary.

From April 2022, the following criteria are considered for technologies to be included in MTFM:

- Are effective: demonstrated through positive NICE Medical Technology Guidance (MTG) or Diagnostic Guidance (DG);
- Are cost-saving within three years of implementation: as demonstrated by NICE modelling and published in a NICE resource impact template;
- Are affordable to the NHS: the NICE budget impact analysis total costs should not exceed £20 million in any of the first three years.

Applicant

No application can be made for inclusion in the scheme. NHS England's delegated team (Innovation, Research and Life Sciences team, IRLS), jointly with NICE, makes a selection on the basis of released medical technologies guidance (MTG) and diagnostics guidance (DG) by NICE.

Stakeholders involved

Stakeholder	Role
NHS Accelerated Access Collaborative (AAC) team	The key operator of the framework
NHSEI Innovation, Research and Life Sciences (IRLS) team	Together with NICE, responsible for identifying innovations and decision-making on inclusion/withdrawal
National Institute for Health and Care Excellence (NICE)	Developing MTGs, Diagnostic Guidance, and tools to support providers of NHS services implementing NICE guidance. Together with IRLS, responsible for identifying innovations and decision-making on inclusion/withdrawal
Academic Health Science Networks (AHSNs)	Support both the product suppliers and NHS providers to engage with local commissioners (Integrated Care Boards) and understand the benefits of implementing MTFM technologies
NHS providers	Implementing MTFM technologies as part of care pathways
Local commissioners (Integrated Care Boards, ICBs)	Funding of MTFM technologies; supporting providers and suppliers' transition from the ITP program to the MTFM policy
NHS Supply Chain	Central procurement

Role of the industry

Suppliers of technologies are collaborating with Academic Health Science Networks, supporting clinicians in their discussions with operational managers and finance colleagues, and developing location-specific business cases for funding. There is no direct formal role in the application/selection process for the MTFM. However, the industry can initiate an HTA at NICE, which is one of the prerequisites for the MTFM process.

Clinical and economic requirements for the scheme

Clinical and economic requirements for entrants are outlined in the criteria for the scheme: supportive Medical Technology Guidance or Diagnostic Guidance from NICE, net saving in the first three years of implementing the technology, and budget impact should not exceed £20 million in any of the first three years.

There are specific clinical standards for the proper implementation of the MTFM technologies as part of a care pathway, which are provided in the MTFM policy for each technology.

Statistics and trends about the use of the scheme

In 2020/21, two technologies were considered as part of the MTFM pilot scheme: HeartFlow (CT-FFR) and SecurAcath.

In 2021/22, four technologies were supported by the MTFM (link):

- Placental growth factor (PIGF) based testing – a blood test to rule out pre-eclampsia in pregnant women;
- SecurAcath – for securing percutaneous catheters;
- HeartFlow FFRCT– to create a 3D model of a patient's coronary arteries and assess the extent and location of blockages, estimating fractional flow reserve from coronary CT angiography;
- gammaCore - a non-invasive vagus nerve stimulation therapy for treating cluster migraine.

In 2022/23, all four technologies covered in 2021/22 continue to be supported, and seven new technologies were added (link):

- Four technologies for benign prostatic hyperplasia treatment: UroLift, GreenLight XPS, Rezum, and PLASMA system. These less invasive innovations allow patients with benign prostate hyperplasia to be treated as day cases;
- Three products for improving the patient experience during procedures as innovative alternatives that are either less invasive or use digital technology to increase efficiency and improve outcomes compared to current procedures:
    - The XprESS multi-sinus dilation system, a sterile, single-use device for treating chronic sinusitis;

- The Spectra Optia, an apheresis and cell collection platform for treating sickle cell disease;
- Thopaz+ portable digital chest drain system that provides regulated negative pressure close to the patient's chest and continuously monitors and records air leaks and fluid drainage.

Reference

Web-link to the scheme.

FRANCE: INTRODUCTION

France has six active innovative payment schemes:

- Article 51 of the Social Security Financing Act, the focus of which is diverse and includes hospital medical devices and procedures, but also non-med tech interventions, such as rehabilitation, psychological interventions, screening methods, digital health technologies for use in home settings, optimisation of care pathways, etc.;
- Health Economic Research Program (Programme de Recherche Medico-Economique, PRME), which equally focuses on drugs and medical technologies and procedures (mostly procedures delivered in in-patient settings and, rarely, IVD tests/screening methods);
- Innovation Funding (Forfait Innovation), which is mostly focused on hospital medical devices and procedures, and IVD tests (rarely);
- List of Biological and Anatomocytopathology Innovative Acts (RIHN) / Supplementary List, which is focused on innovative IVD and genetic tests;
- Provisional registration of medical procedures, which allows for temporary reimbursement of medical procedures delivered in both in-patient and out-patient specialist settings, with the goal of establishing additional evidence needed for permanent reimbursement (permanent registration in the CCAM classification).
- Transitional Coverage of Medical Devices, which allows for temporary reimbursement of medical devices used in in-patient or home care settings, with the goal of establishing additional evidence needed for permanent reimbursement (registration in the LPPR List);

FRANCE: ARTICLE 51 OF THE SOCIAL SECURITY FINANCING ACT

Title

Article 51 of the Social Security Financing Act 2018 (Article 51 de la Loi de Financement de la Sécurité Sociale 2018).

Objective

The objective of this scheme is to improve cooperation between health actors or decrease the partition of the health sector or improve the patient journey, the efficiency of the health system, access to care or the relevance of the prescription of healthcare products through innovative funding (for example, bundled payment) or innovation in the organisation of healthcare.

Overview

Article 51 created the possibility for innovation in financing and organisational schemes in the health care sector. The funding of the French health care system is segmented into community care financing, hospital financing, and medico-social sector financing. The objective of Article 51 is to create a different funding pathway that would encourage innovation. The Article was introduced in 2018.

The projects eligible for funding via Article 51 have to improve access to healthcare, the efficiency of the system, the relevance of prescription, and patient pathway. Thanks to this new approach, the innovative technologies can bypass one or more of the 63 regulations of social security financing laws, whether on the coordination of medical pathways, relevance and quality of health, social or medico-social services, structuration of ambulatory care, and healthcare access.

Projects can be submitted through this pathway only if they can benefit from a derogation from one or more laws detailed in Article 51. The derogation can be on pricing, billing, and reimbursed rules; it can also be on out-of-pocket payment or fee-sharing between practitioners. Some derogations need an assessment by HAS (e.g., temporary accommodation services, heavy equipment, home dialysis). No derogation is possible for practitioner competencies. Possible derogations are described in the table below.

Financial derogations	Organisational derogations
• Every form of hospital payment, medico-social centres, and social services • Every kind of payment applicable in town medicine, pharmacies, health centres, medical devices, transportation, and direct payment by the patient • Payment of fees covered by health insurance • Participation in hospital daily fees	• Rules on fee-splitting between health professionals • Rules for health centres on non-medical residential possibilities • Rules on care authorisation and use of heavy medical equipment

Financial derogations	Organisational derogations
• Payment of drugs and medical devices by health insurance	• Rules on the intervention of services providers or medical devices providers to allow dialysis under supervision by a pharmacist

Three categories of experiments are possible within this scheme:

- Projects on organisation or development of activities (care, prevention, support);
- Projects on organisation or funding of activities (care, prevention, support);
- Projects to improve quality or efficiency of payment by health insurance, of drugs, services, or devices prescription, of funding of innovative medical devices.

The project can be local, regional, or national.

	National projects	Regional/local projects
Organisation and support	FISS	FIR
Evaluation	FISS	FISS
Care services – under derogation	FISS	FIR
Care services – common law funding	Common law	Common law

Experiments within this scheme are financed by the Innovation Fund for Health System (FISS, Fonds d'Innovation pour le Système de Santé), managed by social health insurance. This fund is established with Article 51; it can finance a part or the entire experiment and operational costs following it. The Regional Intervention Fund (FIR) can also be mobilised for project management or reporting. If required, traditional funding can finance the project (health insurance, patients). The multi-year FISS budget provides more than €460 million, and the FIR budget provides more than €15 million for experiments within Article 51.

The experiments can last up to five years, and, depending on their scope and duration, they can receive different amounts of money (from €70 thousand to €21 million). On average, a project receives €1.6 million and covers 2,000 patients. (reference 1, reference 2)

After the completion of the project, it should be possible to make a decision about the implementation of the innovation in the regular care pathway.

Care settings

In-patient, out-patient specialist, and community settings. The emphasis is on the medical technologies that can improve the organisation of care and impact the general well-being of the community.

Type of covered technologies

The focus of the program is diverse and includes hospital medical devices and procedures, but also non-med tech interventions, such as rehabilitation, psychological interventions, screening methods, digital health technologies for use in home settings, optimisation of care pathways, etc.

Inclusion criteria

The projects must meet four criteria in order to receive funding:

- It is of an innovative nature;
- It is feasible;
- It would be possible to perform it on a larger (national) scale;
- It is cost-effective.

It is crucial that the service provided to the population improves their health and that it has a positive impact on the organisations involved. The relevance of the evaluation methods proposed and the operational feasibility will also be taken into account by the decision-makers.

Applicant

There are no restrictions on the applicant. Health institutions (public or private), medical societies, authorities, or for-profit businesses can apply for funding.

Stakeholders involved

Stakeholder	Role
Technical Committee (TC) for health innovation	Linked to the Ministry of Health and Social Security. Analyzes submitted projects and formulates an opinion.
Strategical council (SC) for health innovation	Presided by the Health Minister, receives interim and experimentations reports formulates an opinion on a generalization of the experiment.
Administrator from the strategical council and technical committee	Receives specifications from national or interregional project holders and transmits them to the TC. Organizes and coordinates the work of the TC, referral procedure of HAS, a discussion between the TC and ARS, and provides the opinion of the TC to the Health Minister. Organizes work of the SC under the supervision of the president and transmits its recommendations.
Regional Health Authorities (ARS)	Receive and select specifications of regional and local stakeholders. The Director of ARS provides their opinion to the rapporteur and publishes a decree if the opinion of the TC is positive.

Stakeholder	Role
	ARS can also receive applications for national projects and transmit them to the rapporteur.
The National Authority for Health (HAS)	Gives recommendations for some specific derogations, for example, fee sharing, residency, home dialysis, use of heavy equipment, etc.

Role of the industry

The industry can lead the projects (i.e., can apply for inclusion in the scheme). However, in reality, there are very few projects driven by the industry.

Clinical and economic requirements for the scheme

There are no specific clinical or formal economic requirements that the suggested experiments must meet in order to receive financial support via Article 51. However, the experiments must fulfil the abovementioned criteria, including cost-effectiveness.

Statistics and trends about the use of the scheme

Statistics for 2018-2021

The Strategical Council report from January 2022 provides full statistics for the period 2018-2021 (link).

In the period from April 2018 – until the end of 2021, 967 applications for projects (both on the national and regional levels) were submitted. Out of those submitted, 232 were related to healthcare products (medical devices and pharmaceuticals) and digital tools (24%). Out of those submitted, 570 (59%) were eligible and reviewed. Out of those eligible and reviewed, 103 projects (18%) were ongoing, and 213 (37%) were under review (as of the end of 2021). More statistics about this scheme are presented below.

Aspect	Statistics
Targeted patient groups (based on the analysis of the 570 eligible projects)	• 30% – elderly • 25% – children • 45% – other patient groups (handicapped, adults, women and neonates, other)
Applicants who applied for the projects (based on the analysis of the 570 eligible projects)	• 35% – healthcare facilities (public or private) • 20% – clinical associations • 14% – ambulatory care providers • 8% – manufacturers • 23% – all other stakeholders
The setting of the submitted projects (based	• 39% – mixed (ambulatory/hospital) setting • 38% – ambulatory setting

Aspect	Statistics
on the analysis of the 570 eligible projects)	• 12% – hospital (specialist) setting • 7% – social care setting • 4% – other
Most common treatment areas of the projects (based on the analysis of the 103 ongoing projects)	• 10 – obesity • 8 – oral health • 8 – clinical situations related to ageing • 6 – addiction • 6 – cancer • 6 – cardiovascular • 5 – mental health
Number of projects by the approved duration (based on the analysis of the 103 ongoing projects)	• 48 – 4-5 years • 36 – 2.5-4 years • 19 – 1.5-2.5 years
Number of ongoing projects by region (one project can be conducted in several regions)	• >30 – 3/18 regions (Occitania, Auvergne-Rhône-Alpes, Île-de-France) • 20-30 – 5/18 regions • 15-20 – 3/18 regions • <10 – 7/18 regions (Corsica, Normandy, and overseas territories)
Statistics related to telemedicine	• Out of 967 submitted projects, 232 were related to healthcare products (medical devices and pharmaceuticals) and digital tools • Out of these 232 projects, 118 were related to telemedicine (2 were related to drugs, 58 were related to medical devices, and 58 were related to digital non-medical device tools) • Out of these 232 projects, 96 projects were related to medical devices (5 related to IVD tests, 8 were individual MDs, 13 were connected MDs, 22 were medical equipment, and 48 were digital medical devices) • Out of these 232 projects, 114 were rejected/abandoned • Out of 118 projects related to telemedicine, 22 were approved, 50 were still being evaluated, and 46 were rejected/abandoned

Selected projects under Article 51

There are two groups of experiments under Article 51: those initiated by the Ministry of Solidarity and Health and those initiated by other stakeholders (public or private hospitals, medical societies, authorities, and for-profit businesses).

As of July 1, 2022, in total, 96 experiments were initiated by different stakeholders, including one experiment that started in 2018, 33 experiments that started in 2019, 32 that started in 2020, 25 that started in 2021, and five that started in 2022:

- COCON - Early and coordinated care pathway for vulnerable newborns;

- Tende Pharmacy Antenna - Establishment of a pharmacy annex following the closure of the Tende pharmacy;
- SIIS - Intensive Monitoring for the Social Inclusion of people with disabling mental disorders and frequently hospitalised in psychiatry in two areas of the city of Marseille;
- OdySight - Promote access to ophthalmological care with a remote monitoring medical application allowing the self-assessment of visual parameters;
- Inspir'Action - Innovative rehabilitation care pathway in chronic obstructive pulmonary disease;
- VIGIE AGE - Creation and evaluation of geriatric care network for the home care of elderly patients with multiple pathologies in an unstable condition in Île de France;
- CAMI SPORT and CANCER - Coordinated program and fixed payment of physical activity for therapeutic purposes in oncology;
- EDS Pterygium - Integrated course for pterygium surgery under local anaesthesia in an office in French Guiana;
- BASE - Accompany the future and young parents to adjust to the essential psychoaffective needs of the child by deploying universal and multidisciplinary preventive care pathways in the antenatal/perinatal period and during early childhood in Nouvelle Aquitaine;
- TRANSPORTS FNMS - Optimisation of the efficiency of the organisation of medical transport in the Grand Est, New Aquitaine, Occitanie, and PACA regions;
- LYMPHORAC 51 course - Coordinated care pathway for patients suffering from lymphedema;
- CLIN AVENIR - Setting up outpatient chronic disease clinic run by the ClinAvenir Alliance in Toulouse;
- PRECIDIVE - Prevention of severe chronic disease recurrence by changing diet and physical activity;
- RR TELEDOM-Rehabilitation - Support of patients with chronic obstructive pulmonary disease (COPD) hospitalised for an Acute Exacerbation of COPD; support is provided through a Home Respiratory Rehabilitation program and Tele-Rehabilitation in Haut de France;
- RÉMIDOM - Joint and coordinated care of patients with long-term illnesses by private nurses and general practitioners in Pays de la Loire;
- TIMÉO - Innovative Multidisciplinary Assessment for Obesity Treatment;
- DENTAL EMERGENCIES - Integration of dental surgeons in the regulation of Emergency Service Center 15 on Sundays and public holidays in Auvergne-Rhône-Alpes, Bourgogne-Franche-Comté, Brittany, Centre-Val de Loire, Grand Est, Hauts-de-France, Ile-de-France, Normandy, New Aquitaine, Pays de la Loire;
- DSPP CHILDREN - Shared care system in pediatric and adolescent psychiatry in Hérault;
- AKO@dom/PICTO - Human and digital support for cancer patients after initiation of drug therapy and/or immunotherapy in the Grand Est region;

- WALK HOP - Cardiac telerehabilitation for coronary patients stabilized after acute disease and with a low risk of rehabilitation outside the post-acute care and rehabilitation activities;
- READ'HY - Cardiac Rehabilitation Program with remote monitoring and weekly face-to-face evaluation;
- ARGOS 2 - System of care for homeless drug users in the Grand Est region;
- The ProxOb program - Interdisciplinary care in home settings for families with overweight children;
- CHIK TAMBOUYE - Care pathway for patients with chronic Chikungunya in Guadeloupe;
- EXPRESO - Prevention in oral health with the aim to improve the oral and general health of young adults of 18-21 years by taking charge of pathologies at their early stage;
- GPSO - Management of obesity for the early care provision and long-term support for adults with obesity;
- PHARM OSYS - experiment for the response provided to identified first-aid situations (cystitis, tonsillitis, etc.) by community pharmacists in areas of medical under-density;
- EVA CORSE - cardiac rehabilitation program in the Corsica region;
- METIS CONNECT - Digital follow-up of patients with cancer of the gastrointestinal tract undergoing chemotherapy inter-courses in Auvergne - Rhône – Alpes;
- Post-COVID microstructures to strengthen the medical microstructures, made up of one or more general practitioners, a psychologist, and a social worker within the medical practice, so that they ensure, for somatically, socially, and psychologically weakened patients, local multi-professional care with the support of a psychiatrist and in partnership with actors in the field of mental health in the regions;
- Parcours denutrition Bretagne - personalized and coordinated care course for undernourished patients in Ille-et-Vilaine;
- APA - Adapted physical activity after cancer that sets up a physical activity program adapted to post-breast cancer and cancer of the gastrointestinal tract according to new methods combining face-to-face and remote sessions;
- FNMF Prediabetes - implementation of a package for the management of prediabetes by a multidisciplinary team within mutual health care structures;
- BARIA UP - Support path for obese patients after bariatric surgery in the areas of Lille, Lyon, and Toulouse;
- PAP DOP - experiment provides financial incentives for healthcare professionals and organisations to prevent and take charge of undernutrition before and after the patient's hospitalisation to improve the results of surgical interventions;
- THÉRAPIES ORALES (ORAL THERAPIES) - experiment with the focus on home monitoring of patients on oral cancer drugs;
- Parcours Nutri'Age (PNA) - prevention, screening, and management of undernutrition and risky situations in a multi-professional city hospital team in Haut de France;
- DNUT - home care pathway for undernourished people over 60, which sets up a home care pathway for the undernourished patient by a multi-professional team including dietetic and

physical care, coordinated and monitored by the registered nurses in support of the doctor treating the patient;

- PASCIA`MANS - innovative coordinated accompanied health course adapted for precarious patients with a low level of literacy in the Southern Quarters of Le Mans;
- LENA - implementation of a coordinated course of preparation for discharge from hospitalisation and return home with the possibility of accommodation in assisted transitional accommodation in an independent residence;
- PRIMORDIAL - experiment on the new fixed-price financing model resulting from the PEPS experiment to newly created health centres for primary care;
- DRAD - experiment offers a solution to elderly people with a loss of autonomy who wish to stay at home, for whom "classic" support from home services is not anymore sufficient;
- MEDISIS - Course to secure the medication management of patients specifically at transition points considering cases with an increased medication errors risk;
- DSPP - Psychiatric care system in Haute Garonne;
- Regional management of gestational diabetes around remote monitoring – Brittany;
- TOPASE – Regional Pediatric Obesity Unit in Center-Val de Loire;
- OPTIMED – Optimisation of drug prescriptions in the care pathway for the elderly in Ile-de-France;
- PASSCOG - Ambulatory course for patients with cognitive disorders;
- CDS SOYAUX - Experimentation of the Soyaux clinical multipurpose health centre;
- CATARACTE - Experimentation to promote transparency and relevance for cataract surgery in the territories of Nantes and Limoges;
- OCTAVE - Experimentation carried out by the Regional Unions of Health Professionals (URPS) pharmacists from the Brittany and Pays de Loire regions;
- ANGELE - Complex allergies: global, dietary, and environmental care;
- DIAB-eCARE: Outpatient installation of an external insulin pump in adolescents and adults with type 1 diabetes in an expert centre for integrated practices in Auvergne-Rhône-Alpes;
- TSLA OCCITANIE - Experimentation relating to specific language and learning disorders;
- Respiratory rehabilitation programs coordinated at home carried by the Partn'Air (Toulouse) and Air+R (Montpellier) associations;
- "As du Cœur" – Experiment with adapted physical activity for cardiovascular patients;
- HandiCOnsult'34 – Consultation unit dedicated to people with disabilities in Occitanie;
- Liberal light structures for the rehabilitation of coronary and heart failure patients;
- IPSO – New general practitioner contract in Île-de-France;
- Home follow-up of cancer patients treated by immunotherapy (Center Léon Bérard) in Auvergne Rhône-Alpes;
- City-hospital coordinated perinatal course in the context of a physiological pregnancy (Hospi Grand Ouest);
- SPADepress – Coordinated pathway for patients with depression between primary care and psychiatry in Pays de la Loire;

- Promotion of alimentation and physical activity – INEgalités de Santé en Guadeloupe et Iles du Nord (PRALIMAP);
- Pathway for patients with severe heart failure in Île-de-France;
- CoPa parental coaching in Grand-Est;
- Identification of weaknesses and prevention of worsening health in elderly in Occitanie;
- Obepar – Bariatric surgery course in Île-de-France;
- Gecoplaies – Close support for patients with chronic and/or complex wounds in the Indian Ocean;
- Equip'addict "Harmonized development of the device of medical addiction microstructures" in Burgundy France Comté, Occitanie, Hauts de France, Île-de-France;
- Optimisation of drug prescriptions in the care pathway for the elderly in Hauts-de-France;
- Coordinated experimental care pathway for chronic renal failure patients referred for conservative treatment in Hauts-de-France;
- AFM Téléthon – Innovative support organisation for people with certain disabling diseases, with disabilities;
- TokTokDoc – Mobile polyclinic in Grand Est;
- Di@pason – Care pathway integrating delocalized biology for chronic patients under anti-vitamin K anticoagulants;
- OPTIM CARE – Medical telemonitoring of liver transplant patients;
- Early detection and improvement of the monitoring of renal failure by medical biologists in Center Val de Loire;
- Passport BP – Care pathway for bipolar patients;
- Ildys – Mobile oral care service in Brittany;
- Screening and diagnosis of oral dental problems in people with reduced mobility in health and social medical establishments in the Cher;
- CICA'Corse – Close support for patients with chronic and/or complex wounds in Corsica;
- CeSOA – Outpatient bone and joint care centre in Île-de-France;
- PSYCOG – Intervention of a psychologist with the patient and/or the caregiver in the personalized journey of people with cognitive disorders linked to Alzheimer's disease or related diseases;
- RSMO – Home care for disabled and/or elderly people by attending physicians and nurses in Pays de Loire;
- PACO – Bariatric surgery course in the Paca region;
- PEGASE – Standardized health protocol applied to children who benefited from a child protection measure before the age of five;
- EQUILIBRES – Responsible and solidarity free nursing teams;
- Management by remote monitoring of gestational diabetes;
- Domoplaies – Close care of patients with chronic and/or complex wounds in the Occitanie region;

- Migrant health consultations – development of professional interpretation in town medicine in Brittany;
- Simplification of the Hepatitis C care pathway in vulnerable populations;
- DEPIST'C PHARMA – Simplification of the hepatitis C care pathway in populations at risk;
- SBDM – Mobile oral care service for EHPAD residents in Puy-de-Dôme;
- UFSBD – Support and oral prevention for people living in residential facilities for the elderly;
- Vabres – Coordinated care pathway for protected children and adolescents;
- EMNO – Improvement of the health of a patient suffering from obesity in Dijon and its surroundings;
- DiVa (Dijon Vascular Project) for intensive joint monitoring of stroke and myocardial infarction by nurses, doctors, and pharmacists, hospital, and liberal in the GHT 21-52.

As of July 1, 2022, in total, 16 experiments were initiated by the Ministry of Solidarity and Health, including three projects started in 2018, six projects started in 2019, two started in 2020, three started in 2021, and two started in 2022:

- ICOPE - Program of autonomy loss prevention focused on multidimensional screening for age-related functional deficit;
- FACILISOINS - Health package for people with disabilities in an establishment or medico-social service;
- SEC - Participation Coordinated Exercise Structures;
- RéPAP - Personalized perinatal support for women;
- EqLAAT Local Support Teams on Technical Aids - experiment with setting up local teams quickly and easily accessible, independent of all commercial activities on technical aids, for the assessment and support of the choice and the handling of technical aids for people with disabilities and the elderly;
- Community-based sexual health centres;
- Emergency reorientation package;
- OBEPEDIA – Care pathway for children and adolescents with severe obesity;
- Experimentation with a payment by a team of city health professionals – PEPS;
- Experimentation with an incentive for shared care – IPEP;
- Experimentation with payment per episode of care for surgical treatment – EDS;
- Experimentation to encourage the hospital prescription of similar biological drugs when they are dispensed in town;
- Experimentation changing the methods of use and management of expensive drugs administered by health establishments;
- An experiment on the care of young people with psychic suffering (2017) – integrated into Article 51;
- An experiment in the care and follow-up of children at risk of obesity (2016) – integrated into Article 51;

- PAERPA – Experiments relating to the health care pathway of elderly people at risk of loss of autonomy (awarded in 2013) – integrated into Article 51.

Reference

Web-link to the scheme.

FRANCE: HEALTH ECONOMIC RESEARCH PROGRAM (PRME)

Title

Health Economic Research Program (Programme de Recherche Medico-Economique, PRME).

Objective

The objective of the PRME program is to support the initiatives of French hospitals to validate the clinical and health-economic value of innovative medical technologies, procedures and drugs.

Overview

Health Economic Research Program (PRME) is coverage with the evidence development program in France. The program focuses on drugs, medical technologies and procedures (mostly procedures delivered in in-patient settings and, rarely, IVD tests/screening methods).

In the process, the Ministry of Health calls for proposals annually in December. Researchers need to submit a Letter of Intent, which includes a form of the short version of the research protocol, by March-April of next year. The pre-selection of the application is made by June by responsible parties. During the July-September period, applicants need to submit a full protocol. During November-December, a final decision about the selection of research projects is made. From the beginning of the next year, researchers can receive funding for the study.

The program only considers products for which their clinical effectiveness and safety have been demonstrated before in French or international studies. Eligible products are at the stage of initial distribution and marketing.

The main objective is to demonstrate clinical and health economic utility for innovation, for which clinical effectiveness was previously validated.

After the completion of the program, it should be possible to make a decision regarding whether or not sufficient expected benefits for a studied method are available, which would enable reimbursement either via DRG for the procedure described using a CCAM code or via add-on reimbursement for implants and invasive devices via LPPR List.

The government fully sponsors the program. In 2021, a total of €4 million was awarded (a total of six projects; on average €667,000 per project).

The design of the study is typically a randomised controlled trial combined with a health economic assessment. The typical duration is up to two years. All projects should study health economic consequences according to the standards defined by HAS, typically in the form of cost-effectiveness analysis. A health economist and methodologist should systematically be involved in the development of the protocol.

Specifics of the study design include:

- The comparator should be a relevant standard of care in France. If multiple comparators exist, they should be presented in the study;
- Health economic study is mandatory and should follow methodological requirements outlined by the National Authority for Health (HAS);
- Projects should be multicenter projects and include a minimum of five and a maximum of ten centres;
- The allocation budget should explicitly cover the additional cost of the innovation;
- If the initiation of the project suffers an unjustifiable delay, it may result in the termination of funding;
- The Ministry of Health should approve any major violations of the agreed protocol. In case of non-compliance, financing can be stopped.

PRME program has two dimensions:

- "Health innovation" dimension to demonstrate the efficiency of technology for HAS;
- "Care pathway" dimension to compare the effectiveness of management practice in real life versus standard of care.

Previously, there were two calls for proposals: National PRME projects and cancer-related PRME projects. Since 2017, there has been a call for proposals for National PRME projects only.

The call for proposals is not topic-specific, and any topic is considered.

Care settings

Mostly in-patient settings, but some examples of out-patient specialist settings (including screening methods) were also present in the past.

Type of covered technologies

Medical devices and procedures, pharmaceuticals. Rarely, IVD tests.

The only example of the inclusion of an IVD test in the scheme is the cost-consequence analysis of screening for streptococcus B per partum by PCR versus by the antenatal culture at 34-38 weeks in the optimisation of antibiotic prophylaxis per partum.

Inclusion criteria

The following inclusion criteria for the program exist:

- Safety and efficacy of technology have been previously validated in clinical research;
- The project must meet the following characteristics:
    - When quantity and quality of data permits, available data shall be collected in the form of a systematic literature review; when relevant data are not available, pragmatic quasi-experimental studies and the use of the medico-economic database can be considered; perform budget impact analysis when necessary.

    - Includes cost-utility analysis; comparator reflects currently recommended standard of care when a major budget impact is anticipated; formal budget impact analysis should be performed; involved institutions should provide all necessary cost data to successfully complete the project; the project should preferably be multicentered;
- Technology should be CE-marked;
- Technology should optimise the care pathway.

Technologies previously evaluated by HAS should not be considered in the PRME program, regardless of the outcome of the evaluation.

Applicant

Researchers within hospitals.

Stakeholders involved

The following stakeholders are involved.

Stakeholder	Role
Ministry of Health	Determines the scope and priorities of the program in the annual circular Provides funding for the research program
Interregional Groups of Clinical Research and Innovation (GIRCI)	Assist with the development of the letter of intent
Institutional Jury for pre-selection of the applications	Includes representatives from the Ministry of Health (DGOS, DSS, DGS), National Authority for Health (HAS), National Health Insurance Fund for Employed Workers (CNAMTS) Performs pre-selection of the applications
Scientific jury for the final selection of the applications	Consists of two clinicians and one health economist Makes final selection/appraisal of the full protocols
Researchers within hospitals	File a letter of intent, submit a full proposal for research funding, perform the study
National Agency for Research (ANR)	Maintains the website with a list of all open calls for proposals for research funding

Role of the industry

The manufacturers do not have any direct role in this scheme.

Clinical and economic requirements for the scheme

The technology should have proven efficacy and safety, which can mean having a comparative study, preferably in the form of a randomised controlled trial.

Statistics and trends about the use of the scheme

As of July 1, 2022, the latest available statistics are for the year 2021 (projects are awarded at the end of the year) (link).

Category	2018	2019	2020	2021
Total number of selected projects (including drugs)	8	12	9	6
Number of selected projects for medical technologies	6	7	5	3

In 2019, there were 12 projects awarded in total in the PRME program, including seven (58%) projects related to medical technologies (other projects focused on game therapy, management strategies and pharmaceutical products):

- A randomised medico-economic trial comparing focal HIFU treatment with total prostatectomy in patients with intermediate-risk prostate cancer;
- Cost/utility analysis of fenestrated aortic stents versus open surgery for the treatment of para-renal aortic aneurysms: a prospective comparative multicenter cohort study;
- Medico-economic evaluation of fluocinolone acetonide implant versus dexamethasone implant in resistant diabetic macular oedema;
- Vagus nerve stimulation and resistant depression: a multicenter, randomised, open-label medico-economic trial;
- Evaluation of the efficiency of the Cerament-G bone substitute delivering gentamicin locally in the treatment of osteomyelitis of long bones: a multicenter national study in the CRIOAc network;
- Cost-consequence analysis of screening for streptococcus B per partum by PCR versus by the antenatal culture at 34-38 weeks in the optimisation of antibiotic prophylaxis per partum;
- Medico-economic evaluation of two diagnostic imaging strategies, MRI versus CT scan in patients suspected of ischemic stroke: a prospective, controlled, randomised study.

In 2020, there were nine projects awarded in total in the PRME program, including three (33%) projects related to medical technologies (other projects focused on physical activity programs, management and surveillance strategies):

- Medico-economic evaluation of the first-line coronary CT scan strategy compared to the first-line functional test strategy in patients at intermediate risk of stable coronary artery disease: a prospective, controlled, randomised clinical trial;
- Randomised study of costs and effectiveness of routine hepatic fast-MRI surveillance for the detection of early-stage hepatocellular carcinoma in high-risk patients enrolled in ultrasound surveillance programs;
- Post-treatment monitoring of metastatic colorectal cancers in complete response at high risk of recurrence: prospective, randomised evaluation of the medico-economic impact of monitoring by whole-body MRI alone.

In 2021, there were six projects awarded in total in the PRME program, including three (50%) projects related to medical technologies (other projects focused on psychological interventions, management strategies and pharmaceutical products):

- Health-economic evaluation of the surgical treatment of osteoarthritis of the base of the thumb by the implantation of a total trapezio-metacarpal prosthesis compared to the surgical treatment of reference (trapezectomy): prospective study and Markov modelling;
- Health-economic evaluation of robot-assisted laparoscopy versus laparoscopy in hysterectomies for endometrial cancer: a multicenter randomised controlled trial;
- Health-economic evaluation of a mobile hybrid room in vascular surgery.

Number of selected technologies for the last eight years

The number of selected technologies for 2014-2021 by type of the PRME program are presented below (for drugs and medical technologies combined).

Type of program	2014	2015	2016	2017	2018	2019	2020	2021
PRME	11	8	7	10	8	12	9	6
PRME-K	4	4	2	-	-	-	-	-
PRME Total	15	12	9	10	8	12	9	6

Reference

Web-link to the scheme.

FRANCE: INNOVATION FUNDING (FORFAIT INNOVATION)

Title

Innovation funding (forfait innovation).

Objective

The objective of the program is to provide early support for breakthrough innovation and bridge serious evidence gaps simultaneously. The scheme can be classified as coverage with evidence development program.

Overview

Innovation Funding / forfait innovation is the most advanced coverage with the evidence development program in France. The program was initiated in 2015 and is only focused on medical devices, procedures and in-vitro diagnostic technologies.

The pathway includes a government co-sponsored study. The budget comes from three sources: the Ministry of Health (experimental arm), regular statutory health insurance (control arm), and an applicant (study infrastructure). In the process, the applicant (manufacturer) develops an application submitted to the Ministry of Health and the National Authority for Health (HAS). After evaluation and negotiations, the funding can be granted.

The process includes the following steps and timelines:

- The applicant receives the confirmation of receiving the application by HAS within 15 days of application;
- Then, it takes HAS 75 days to decide on the eligibility and feasibility of the project (with potential 30 days given to the applicant in case of insufficient information submitted);
- In case of a positive opinion for the project but with comments, the applicant has 30 days to submit additional information;
- Then the HAS has 30 more days to make the final decision;
- The budgeting phase (for each project agreed upon) takes 75 days (or 45 days in case of a positive opinion with comments). In this phase, the applicant may be given up to 30 days for submission of additional information;
- Finally, the publication of the Order that approves the project takes 30 more days.

The sample size and the budget for the Innovation Funding framework can be substantial:

- 5100 patients in the study of high intensity focused ultrasound for prostate adenocarcinoma (total budget impact is about €3,600,000);
- 36 patients in the study of Argus II (total budget is about €3,500,000);
- 4500 patients for the METAglut1 by METAFORA (total budget is about €1,395,000);

- 224 patients for dNerva targeted denervation system of the lungs (total budget is about €699,000).

The budget for the project includes the following three sources of financing:

- Flat rate payment per patient provided by the state for the innovation treatment arm
  - €6,047 for high intensity focused ultrasound for prostate adenocarcinoma;
  - €95,897 for Argus II for retinopathy;
  - €310 for the METAglut1 test for GLUT1 glucose transporter deficiency syndrome;
  - €3,119 for dNerva targeted denervation system of the lungs for chronic obstructive pulmonary disease.
- Reimbursement of intervention in the control arm via regular reimbursement tariffs;
- Financing the clinical trial by the applicant.

The duration of the project can differ: some projects lasted six months, while others lasted up to five years. The clinical trial should be designed to allow a decision about sufficient expected benefits for a studied method to enable reimbursement either via DRG for the procedure described using CCAM/NABM code or via add-on reimbursement for implants and invasive devices via the LPPR List.

Care settings

In-patient and out-patient specialist settings. Previous decisions in the scheme mostly concerned hospital technologies and IVD tests.

Type of covered technologies

Medical devices, medical procedures, and in-vitro diagnostics.

Inclusion criteria

Ministry of Health established the following mandatory criteria:

- The innovative character of technology
  - Not a simple technological evolution;
  - The early phase of diffusion;
  - Characterized risks for patients;
  - Major clinical benefits;
- Proposal of a relevant study
  - The proposed clinical or medico-economic study makes it possible to collect all missing data in order to establish the expected benefit of the method. Studies are comparative except for cases with no relevant comparator or impossibility due to ethical reasons;
  - Other similar studies are ongoing or planned, which will help evaluate the relevance of the French state-sponsored study;

- The feasibility of the proposed study seems reasonable, given the proposed protocol and budget.

However, the program is rapidly evolving, and the criteria might change.

Applicant

The manufacturer makes an application in relation to medical devices and clinical society (represented by their "Collège National Professionel") in relation to procedures.

Stakeholders involved

The following stakeholders are involved.

Stakeholder	Role
Ministry of Health	Decides about funding
National Authority for Health (HAS)	Advises about the selection of the projects and makes a key contribution to clinical protocol

Role of the industry

Prior to submission of the proposal, the manufacturer should make early contacts with the French High Authority for Health (HAS) and/or Ministry of Health and Solidarity (DGOS, Office PF4) to discuss issues related to the methodology of the study and process of the study in general. The manufacturer develops and submits the application to both the Ministry of Health and HAS simultaneously. The applicant also finances the research framework (protocol, analysis) of the study.

Clinical and economic requirements for the scheme

The program focuses on emerging technologies for which data about efficacy and safety are available. However, there are still some gaps regarding clinical and economic evidence that prevent the technology from broader adoption in France.

Statistics and trends about the use of the scheme

As of July 1, 2022, 14 methods were granted Innovation Funding/forfait innovation, and the approval for financing of the procedure/device was announced in the Official French Gazette (Journal Officiel de la République Française) (with the year of release):

- Ultrasound-Guided High-Intensity Focused Ultrasound (HIFU) destruction of localized prostate cancer (2014);
- Argus II for the restoration of limited vision (2014);
- Robotic application of high intensity focused ultrasound (HIFU) with ultrasound guidance (ECHOPULSE) for non-invasive treatment of breast fibroadenomas (2017);

- METAglut1 METAFORA for the diagnosis of the GLUT1 Deficiency Syndrome (2018);
- Subretinal implant RETINA IMPLANT Alpha AMS (2018);
- PULSANTE for the treatment of cluster headache (2019);
- WISE CRT for cardiac resynchronization therapy (2019);
- dNerva targeted denervation system of the lungs (2019);
- BrainPort Vision Pro electronic assistance system for patients suffering from blindness (2019);
- Tests for the detection of the SARS-CoV-2 genome by gene amplification on a saliva sample (2020);
- The CARMAT artificial heart (2020);
- The eCLIPs implant for the treatment of intracranial bifurcation aneurysms (2020);
- Functional test ONCOGRAMME for the management of inoperable metastatic colorectal cancer (2021);
- SUNRISE system of assistance in the diagnosis of obstructive sleep apnea-hypopnea syndrome (2021).

As of July 1, 2022, five methods received a positive recommendation from HAS but have not been yet included in the scheme (their future is unknown):

- Endoscopic gastroplasty with the help of the ENDOMINA triangulation platform (2022);
- Bronchoscopic system for lung volume reduction using water vapour INTERVAPOR (2022)
- Detection of SARS-CoV-2 N-antigen in a blood sample (2021);
- PICSO for intermittent occlusion of the coronary venous sinus to reduce the size of myocardial infarction in patients with left coronary arteries lesions (2018);
- Epi-retinal implants IRIS II (2017).

As of July 1, 2022, the following eleven technologies were considered but did not receive positive recommendations from HAS:

- REZUM minimally invasive treatment for bothersome moderate-to-severe lower urinary tract symptoms associated with benign prostatic hyperplasia (2020);
- NovaGray RILA Breast and Prostate tests (2020);
- ABLUMINUS drug-eluting coronary stent system (2020);
- PRIMA BIONIC VISION SYSTEM subretinal implant (2020);
- STIMROUTER peripheral nerve stimulation system (2020);
- Endoscopic gastroplasty with the help of the ENDOMINA triangulation platform (2021);
- Unilateral MRI-guided destruction of the intermediate ventral thalamic nucleus using high intensity focused ultrasound in stereotactic condition (2021);
- Transcutaneous system of repair of tricuspid mitral valve PASCAL (2021);
- Non-invasive software that allows calculating the value of the fractional flow reserve FFRct (2021);
- GENIO hypoglossal nerve stimulation system (2021);

- DERMAREP biological matrix for wound healing (2021).

Reference

Web-link to the scheme.

FRANCE: RIHN / SUPPLEMENTARY LIST

Title

List of biological and anatomocytopathological innovative acts outside the nomenclature (Le référentiel des actes innovants hors nomenclature de biologie et d'anatomocytopathologie, RIHN) and Supplementary List (Liste Complementaire).

Objective

The objective of the scheme is to provide temporary funding for innovative in-vitro diagnostic tests until evidence is sufficient to incorporate them into the Nomenclature of medical biology acts (Nomenclature des Actes de Biologie Médicale, NABM), which determines coverage within statutory health insurance. The scheme can be classified as a borderline between coverage with evidence development program and innovation funding because requirements for clinical study are not clearly defined.

Overview

RIHN List is the only dedicated innovation funding scheme for IVD and genetic tests in Europe.

In France, IVD tests, eligible for reimbursement within statutory health insurance, shall be included in NABM Nomenclature. Only well-established and validated tests are allowed for inclusion in the Nomenclature. However, the process of inclusion of novel tests is very lengthy (up to five years) and includes evidence review by the National Authority for Health (HAS) and price-setting negotiation/decision by the National Union of Health Insurance Funds (UNCAM).

RIHN was created to provide access to innovative IVD tests that do not have enough data to justify inclusion in NABM Nomenclature. Historically, innovative IVD tests were included in the informal so-called Montpelier List, which was the foundation for extra funding of innovative technologies. However, in 2015, the List was replaced with the RIHN List and the Supplementary List.

Funding of the tests under the RIHN is provided from the budget for research and innovation (MIGAC, the sub-budget of MERRI G03), which is distributed to hospitals by the Ministry of Health. Thus, these are always reimbursed on top of the DRG tariff (even in hospital settings). Each hospital receives a certain amount of money from the MERRI G03 budget 2-3 times a year, which can be used to cover the costs of innovative tests on the RIHN List. In 2021, the total amount of the MERRI G03 budget was €406 million.

The Ministry of Health is responsible for the update of the RIHN List. Applications for the RIHN list are typically submitted in September, and an updated RIHN list is released in March of the following year.

In theory, IVD tests are included in the RIHN for a period of three years with the possible extension of inclusion of up to five years. At the end of the evaluation period, the applicant should submit a

report with information about updated knowledge about the product, clinical evidence, and budgetary impact. The idea of the RIHN List is to be an innovation funding solution until sufficient evidence is collected so the test can be regularly reimbursed by being included in the NABM Nomenclature. However, since the establishment of RIHN, only one test has been integrated into NABM.

There is another concept which is called the Supplementary List. The Supplementary List is independent of the RIHN List, and it contains no longer innovative tests, which were historically reimbursed as innovations, but which do not longer qualify as innovations. The tests in the Supplementary List are likely to be subject to an evaluation by the HAS, with the goal of deciding whether to discontinue their reimbursement or to award them regular reimbursement (inclusion in the NABM Nomenclature). However, the concept of the Supplementary List is out of the scope of this report.

Care settings

Innovative in-vitro diagnostic and genetic tests are delivered in both in-patient and out-patient specialist settings.

Type of covered technologies

Innovative in-vitro diagnostic and genetic tests.

Inclusion criteria

The criteria for enlisting a new test in the RIHN List are:

- The test is innovative;
- The definition should cover all stages of testing (pre-analytical, analytical, and post-analytical);
- Can be funded using MERRI G03 budget (part of MIGAC);
- There is an ongoing research program to evaluate clinical and economic outcomes;
- The test is exempt from the obligation of accreditation.

Applicant

Hospitals (public or private) or entities funded by the National Health Insurance Spending Target (ONDAM) can submit the applications.

Stakeholders involved

Stakeholder	Role
Ministry of Health	Final approval of the List Call for applications
Technical Agency for Hospital Information (Agence technique de l'information sur l'hospitalisation, ATIH)	A clinical and economic evaluation of the dossiers

Stakeholder	Role
Other governmental and independent organisations (HAS, INCA, CNAMTS)	Review of the proposals

Role of the industry

The manufacturers do not have any direct role in this scheme.

Clinical and economic requirements for the scheme

The submitted tests should be in the post-translational research and early dissemination phase. Analytical validation (reliability, accuracy, reproducibility) and initial clinical diagnostic performance of the test should be established, but clinical and health economic validation should still be required for the test.

Statistics and trends about the use of the scheme

The RIHN List is rather stable.

In 2022, no new tests were added to the List. Five codes were removed from the list.

No changes were made in 2021.

One test was added to the RIHN list in 2020.

Nomenclature	Code	Name (English)	Name (French)	Tariff
RIHN V2020	A122	Proteomic analysis based on tandem mass spectrometry after laser microdissection	Analyse protéomique basée sur la spectrométrie de masse en tandem après microdissection laser	€200

Number of tests in the RIHN for the last eight years

Data about the number of IVD tests in the RIHN list are presented in the table below (link).

Nomenclature	2015	2016	2017	2018	2019	2020	2021	2022
RIHN list	240	236	237	237	237	238	238	231

Transfer from RIHN list to NABM catalogue

No codes from RIHN nomenclature were incorporated in NABM nomenclature in the period 2020-2022.

Two tests were moved from the RIHN list to the NABM catalogue – in 2018 (Screening for fetal trisomy) and 2019 (anti-Strongyloid stercoralis antibodies). However, the tests are still registered in

both - RIHN and NABM, but for different indications. The details of NABM registrations are presented in the table below.

Nomenclature	Code	Name	Tariff
NABM v50	4087	Screening for fetal trisomy 21 by analysis of free fetal DNA circulating in maternal blood	€362.88
NABM v50	4088	The second screening of fetal trisomy 21 by analysis of free fetal DNA circulating in the maternal blood	€362.88
NABM v53	1440	Strongyloidiasis: Search for anti-Strongyloid stercoralis antibodies by one technique	€16.20

Reference

Web-link to the scheme.

FRANCE: PROVISIONAL REGISTRATION OF MEDICAL PROCEDURES

Title

Provisional Registration of Medical Procedures (L'inscription provisoire des actes innovants).

Objective

Provisional Registration of Medical Procedures allows for temporary reimbursement of medical procedures via CCAM classification, delivered in in-patient or out-patient specialist settings, so that additional or missing evidence can be generated before obtaining permanent reimbursement (permanent registration in the CCAM classification). This scheme can be classified as coverage with evidence development scheme.

Overview

The Common Classification of Medical Services (Classification Commune des Actes Médicaux, CCAM) is used to code operations, procedures, and interventions in the French health care system. CCAM classification is used for determining payment for medical procedures via GHS (French DRG system) in hospital and day-case settings. Furthermore, the CCAM fees allocated to each CCAM procedure code are used for reimbursement of services provided by physicians in outpatient settings and private for-profit hospitals.

The applications for the creation of new procedure codes are typically submitted by the relevant National Professional Council (CNP). The first step is the evaluation of the application from the clinical perspective, where the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) at HAS evaluates the clinical evidence for safety and effectiveness. In case of recommendations that are positive/positive with reservations, the case is forwarded to the National Union of Health Insurance Funds (UNCAM) for final reimbursement decision-making.

As a part of decision-making regarding granting reimbursement to a new medical procedure and setting the amount of its tariff, the National Union of Health Insurance Funds (UNCAM) asks the High Council of Nomenclatures (HCN) to perform the technical and scientific evaluation of the procedure. The HCN was introduced in April 2021 and started its work in September 2021. Based on the results of the evaluation, the HCN can propose to UNCAM the provisional registration of innovative procedures for three years (with the opportunity of renewal for an additional three years).

Finally, the UNCAM consults with the National Union of Supplementary Health Insurance Organisations (UNOCAM) and makes the final decision regarding the reimbursement of the new service (i.e., registration in the CCAM classification, regularly or provisionally).

The CCAM classification is updated a few times a year. However, the process of introducing a new CCAM procedure code is lengthy (3-5 years).

Provisional registration of medical procedures is just one of the possible outcomes of the application for the creation of a new procedure (CCAM) code (other outcomes are creation of the procedure code or declined application). A specific repository of temporarily reimbursed medical procedures does not exist. The procedures registered provisionally are listed in the CCAM Classification, jointly with other procedures, but with a note that the procedure is covered provisionally.

Once the period of provisional reimbursement is finished (three years), the UNCAM and the HCN will review the situation with the available evidence generated for these procedures. The procedures can either be registered provisionally for three additional years (prolongation possible only once) or be registered regularly in the CCAM classification.

Care settings

In-patient and out-patient specialist settings.

Type of covered technologies

Medical procedures.

Inclusion criteria

There are high evidence requirements for the registration of a new procedure in the CCAM classification.

At least one RCT is required for the creation of the novel procedure code. In addition, studies of other designs can be provided. HAS pays a lot of attention to the quality of the published studies (e.g., loss to follow-up, masking/blinding, method of randomisation). Health economic evidence is not required.

The exact inclusion criteria for *provisional registration* are not entirely clear.

In general, provisional registration in the CCAM classification can be used for innovative technologies for which evidence might not be considered sufficient by the ultimate decision-maker, UNCAM.

The recommendations from CNEDiMTS at HAS for procedures registered provisionally in the CCAM classification can be either positive or positive with reservations.

Applicant

There is no possibility of applying directly for the scheme. Provisional registration of medical procedures is just one of the possible outcomes of the application for the creation of a new procedure (CCAM) code (other outcomes are creation of the procedure code or declined application).

The applications for registration of new medical procedures (creation of new CCAM procedure codes) are submitted by the relevant National Professional Council (CNP). If a CNP for the target field of care does not exist, a clinical society may submit the application. A maximum of three applications per applicant per year are allowed.

Stakeholders involved

The following stakeholders are involved.

Stakeholder	Role
National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) of the High Authority for Health (HAS)	Evaluates the clinical aspects of the procedure and issues an opinion
High Council of Nomenclatures (HCN)	Evaluates the scientific and technical aspects of the procedure and issues a recommendation on whether to register the new procedure in the CCAM classification provisionally or permanently
National Union of Health Insurance Funds (UNCAM)	Makes the final decision regarding granting reimbursement to the new procedure (provisional or permanent), as well as the level of reimbursement tariff for the procedure

Role of the industry

The manufacturers do not have any direct role in this scheme.

Clinical and economic requirements for the scheme

The process of creating new CCAM codes has high evidence requirements.

During the clinical evaluation by CNEDiMTS at HAS, at least one RCT is required for the creation of the novel procedure code. In addition, studies of other designs can be provided. HAS pays a lot of attention to the quality of the published studies (e.g., loss to follow-up, masking/blinding, method of randomisation).

UNCAM also considers the costs of the new service and compares them to the costs of the currently provided services. However, extensive health economic evidence is not required.

Medical procedures that do not have a sufficient level of evidence, according to UNCAM, can be registered provisionally for a period of three years (renewable once) in order to generate the missing evidence, which is needed to obtain permanent registration in the CCAM classification.

Statistics about the scheme

As of July 1, 2022, there were eight CCAM codes for two procedures that were provisionally covered (link, v70 of the CCAM classification):

- Implantation of artificial iris on pseudophakic eye in the sulcus behind an iris remnant and in front of the implant with capsule support;

- Implantation of artificial iris on pseudophakic eye in the sulcus in front of the implant with capsular support with fixation of the sclera;
- Implantation of an artificial iris behind an iris residue with the extraction of the lens and placement of a capsular support implant;
- Implantation of an artificial iris in the sulcus with fixation to the sclera, with the extraction of the lens and placement of a capsular support implant;
- Implantation of an artificial iris on an aphakic eye with fixation to the sclera, with the placement of a sutured lens implant;
- Repositioning of an artificial iris;
- Removal of an artificial iris;
- Unilateral or bilateral spectral angiomammography.

Reference

No particular web-link to the scheme exists. However, the following paragraphs of the Social Security Code provide more details about the scheme:

- Article L162-1-7;
- Article D162-25-1.

Furthermore, the legislation was amended by the following decrees:

- Decree No. 2021-491 of April 21, 2021;
- Decree No. 2021-492 of April 21, 2021.

More information about the High Council of Nomenclatures (HCN) and its work can be found here.

FRANCE: TRANSITIONAL COVERAGE OF MEDICAL DEVICES

Title

Transitional Coverage (Prise en Charge Transitoire) of medical devices.

Objective

Transitional Coverage (Prise en Charge Transitoire) of medical devices allows for temporary reimbursement of medical devices used in in-patient or home care settings, with the goal of establishing additional evidence before applying for permanent reimbursement (registration in the LPPR List only). This scheme can be classified as the unconditional innovation payment scheme.

Overview

In hospital settings, certain categories of devices can be reimbursed on top of the DRG tariff for the procedure. These devices are listed in Titles III (implants) and V (invasive non-implantable devices) of the LPPR List. The LPPR List also defines the framework for reimbursement of devices used in community / home-care settings (titles I, II, and IV of the LPPR list, which cover medical aids and prostheses).

Application for inclusion in the LPPR List is essential for certain types of devices (mainly expensive implants and invasive non-implantable devices), as LPPR List represents the main payment vehicle for medical devices in France in addition to the DRG system. Without add-on reimbursement via LPPR List, some devices with inadequate reimbursement via the DRG system will have limited utilisation in the healthcare system.

There are two types of registration in the LPPR List: registration by brand name and registration in the generic category.

One of the criteria of the process of inclusion of new branded devices in the LPPR List is that the cost of the device should constitute no less than 30% of the cost of the target DRGs. Furthermore, the process of inclusion of new branded devices in the LPPR List has high evidence requirements. The evidence requirements are higher if the creation of the novel reimbursement category is required, compared to obtaining reimbursement for me-too branded products.

The Transitional Coverage of medical devices framework was launched in 2021, and it allows quicker access to patients for innovative medical devices intended for the treatment of rare or serious diseases which are falling under the scope of the LPPR List. During the Transitional Coverage, medical devices obtain reimbursement for one year (with a possibility of renewal) with the obligation to submit an application for regular reimbursement via LPPR List within one year.

Applications for Transitional Coverage are submitted by the manufacturers of medical devices. The decision-making process lasts up to five months, and it involves the following phases:

- Assessment by the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) at HAS and issuing an opinion (45 days);
- Opinion is delivered to the applicant and the Ministry of Health;
- The Minister of Health decides if the technology is eligible for Transitional Coverage (10 days);
- Maximum reimbursement tariff is claimed by the applicant;
- The Minister makes the decision regarding Transitional Coverage (45 days):
    - If the decision is positive, it is published in the Official Journal of the French Republic, and the medical device is transitionally covered;
    - If the Minister does not approve the claimed reimbursement tariff, the applicant has ten days to decide whether to accept or not the newly suggested tariff. If not accepted, no Transitional Coverage is obtained.

The manufacturer must submit an application for regular LPPR reimbursement or renewal of the Transitional Coverage within 12 months of obtaining Transitional Coverage for the device.

A specific repository of devices does not exist. The devices that obtain Transitional Coverage are listed in the LPPR List.

Care settings

In-patient and community / home-care settings.

Type of covered technologies

This framework is applicable to individual CE-marked, presumably innovative medical devices intended for the treatment of rare or serious diseases (or compensation of a disability), which are falling under the scope of the LPPR List (medical aids, health apps, implants, invasive non-implantable devices).

Inclusion criteria

There are three prerequisites for providing transitional coverage to medical devices:

- The device must have a CE-mark;
- The device should not be covered as part of hospitalisation services;
- The manufacturer must submit an application for regular inclusion in the LPPR List for this medical device within 12 months of the request for Transitional Coverage.

The National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) at HAS evaluates the applications and issues an opinion based on five criteria, which were defined by the decree of February 23, 2021:

- The technology is used to manage a serious or rare disease or to compensate for a disability;
- A relevant comparator does not exist (high unmet need);

- The technology is likely to significantly improve the patient's health status or significantly compensate for a disability;
- The technology is likely to be innovative (not just a simple technical improvement versus technologies currently used in the claimed indication);
- The technology is likely to demonstrate (in clinical studies) a clinically relevant efficacy and a substantial effect with an acceptable level of potential adverse effects.

Applicant

The applications are submitted by the manufacturers of medical devices.

Stakeholders involved

The following stakeholders are involved.

Stakeholder	Role
National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) of the High Authority for Health (HAS)	Evaluates the applications and issues an opinion
Ministry of Health and Prevention	Makes final decision regarding the Transitional Coverage of the device, but also regarding the renewal of Transitional Coverage (upon application for renewal) Can also decide whether to accept the claimed maximum reimbursement tariff or to suggest a reduced reimbursement tariff to the applicant

Role of the industry

The manufacturer of the medical device prepares the submission dossier and submits the application.

Furthermore, after obtaining a positive recommendation from the CNEDiMTS at HAS, the manufacturer will also have to claim the maximum reimbursement tariff to the Minister of Health. In case the Minister rejects this tariff and suggests a lower tariff, the manufacturer will have to decide whether to accept the suggested tariff or opt-out of the Transitional Coverage framework.

Clinical and economic requirements for the scheme

The process of creating a new LPPR category requires a high level of evidence. At least one RCT is required for the creation of the novel reimbursement category.

For registration of individual brands in the already established category of the LPPR List, evidence requirements are usually somewhat lower. In principle, either equivalence versus already registered device (ideally, in the RCT) or superiority versus the common standard of care (in the RCT) is

required. In practice, me-too products have a lower evidence base versus the first applicant for the creation of the new LPPR category.

Economic evidence is required only for technologies with claimed Added Clinical Value (ASA) levels I-III and significant impact on health insurance expenditure or organisation of care. Very few (less than 15) devices required health economic evidence in connection to the LPPR List process. There are two main parts of the health economic analysis:

- Cost-effectiveness analysis;
- Budget impact analysis, which is required only for devices having an expected turnover of ≥€50 million during their second year of marketing (reference).

Regarding the application for Transitional Coverage of medical devices, the evidence requirements are lower compared to the regular reimbursement via LPPR List. From the submitted evidence, HAS should be able to draw a conclusion about the potential of technology to improve the patient's condition. However, HAS performs only a high-level review of the evidence (not a detailed review, as in the regular LPPR process).

Health economic evidence is not required for the Transitional Coverage process.

Statistics about the scheme

Since the inception of the scheme until July 1, 2022, four devices were considered for Transitional Coverage (link):

- The following two devices received a positive opinion from the CNEDiMTS:
  - Neovasc Reducer System (in refractory stable angina pectoris) (so far, the only device that has received a reimbursement decision and is included in the LPPR List);
  - Symplicity Spyral (renal denervation catheter for treatment of resistant hypertension);
- The following two technologies were assessed but received negative recommendations from CNEDiMTS:
  - Ascyrus Medical Dissection Stent (AMDS) (aortic stent used in type I dissections according to DeBakey classification);
  - Deprexis (health app for the treatment of depression).

Reference

Web-link to the scheme.

GERMANY: INTRODUCTION

Germany has four active innovative payment schemes:

- G-BA Innovation Fund (Der Innovationsfonds beim Gemeinsamer Bundesauschuss, G-BA) provides resources for innovative models of care and healthcare research on existing care models in the form of pilots before the broader implementation. Projects typically focus on non-med tech interventions (such as optimisation of care processes and pathways, self-care), and rarely on particular medical technologies (medical procedures, in-vitro diagnostic tests, digital health apps, and medical aids for use in community settings);
- Government Co-Funded Clinical Studies (Erprobungsstudie) (137e Trial Regulation), which focuses on medical devices, procedures, and theoretically IVD and genetic tests delivered in hospital and out-patient settings;
- Innovation Funding for New Diagnostic or Therapeutic Methods (NUB), which focuses on drugs, medical procedures, medical devices, and in-vitro diagnostic tests (eligible for the scheme but usually do not receive NUB);
- Provisional listing of Digital Health Applications (DiGA), which is focused on patient-centric digital technologies (health apps).

GERMANY: G-BA INNOVATION FUND

Title

The Innovation Fund of the Federal Joint Committee (Der Innovationsfonds beim Gemeinsamer Bundesauschuss, G-BA).

Objective

The G-BA Innovation Fund provides resources for innovative models of care and healthcare research on existing care models in the form of pilots before the broader implementation. The scheme can be classified as coverage with evidence development program.

Overview

The Innovation Fund in Germany was created in 2015 for the period 2016-2019, with the primary aim to improve health care for policyholders and patients in statutory health insurance (SHI). It is defined by §92a of the German Social Code Book (SGB) V.

The Innovation Committee set up at the Joint Federal Committee (G-BA) has the task of promoting innovative, in particular cross-sectoral, forms of care that exceed the current standard of care. The resources of the Fund are managed by the Federal Insurance Office (Bundesversicherungsamt), but projects are awarded funds based on the decisions of the Innovation Committee.

The Innovation Committee includes three representatives from the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), one representative from the National Association of Statutory Health Insurance Physicians (KBV), one representative from the National Association of Statutory Health Insurance Dentists (KZBV), one representative from the German Hospital Association (DKG), and six other representatives (two representatives of the patients, one representative of the Federal Ministry of Education and Research (BMBF), two representatives of the Federal Ministry of Health, and the impartial chair of the G-BA). The Innovation Committee is advised by the Expert Advisory Board, which:

- Provides recommendations on the content of the funding announcements;
- Conducts rapid assessments of received applications for funding;
- Makes recommendations on funding decisions;
- Before any appraisal of funding announcements or funding applications, the expert board must prove whether there are elements for a conflict of interest.

The Innovations Fund has the potential and is expected to:

- Promote the scientific area of healthcare research to international standards;
- Have a positive impact on care structures of the German healthcare system;
- Enhance the cooperation of different players in the healthcare system;
- Contribute to the creation of a culture of innovation in Germany;

- Contribute to the application of high-quality study designs;
- Establish a culture of evaluation in Germany.

For the initial period (2016-2019), €300 million per year were dedicated to the Innovation Fund (€225 for innovative care concepts and €75 million for care research). Thereafter, the Innovation Fund was extended until the end of 2024, and the funding amount was reduced to €200 million annually from 2020.

Since June 2020, the funding process for new models of care has been conducted in two stages. First, applicants submit a sketch of an idea, presenting the main content of the planned project on a maximum of 12 pages. The Innovation Committee then decides which ideas will be funded for concept development and the preparation of a qualified application (full application). The preparation of a complete application can be supported for a period of up to six months with a grant of up to a maximum of €75,000.

Innovation Fund is a vital instrument to propose and test a novel model of care (including the ones in the form of selective contracts). If the model proves valuable, it can be a subject for further dissemination in the country. The Innovation Committee provides the results of the successfully accomplished projects to various stakeholders responsible for education and quality assurance, to relevant clinical societies, to subcommittees for quality assurance and method evaluation of the G-BA, etc., with recommendations for implementation in standard care.

Care settings

In-patient, out-patient specialist settings, and community settings (home care).

Type of covered technologies

Predominantly non-med-tech interventions (optimisation of processes, intersectoral cooperation, psychological support, etc.), but also medical procedures, in-vitro diagnostic tests, digital health apps, and medical aids for use in community settings.

Inclusion criteria

The new models of care projects must meet the following criteria to receive funding:

- Improvement of healthcare:
    - Improvement of the quality of care and/or remedy of care shortcomings;
    - Improvement of care efficiency;
    - Optimisation of the cooperation within and between different care areas, care organisations, and professions;
    - Interdisciplinary care models;
    - Transferability of knowledge (findings):
        - To different regions;
        - On indications;

        - On care scenarios;
- Implementation potential:
    - Scope of feasibility, the necessary steps for the implementation, and the transferability of the framework conditions chosen within the project;
- Evaluability:
    - Methodological and technical capacities and independence of the parties involved;
    - Sustainable and outcome-oriented evaluation concept;
    - The results of the project and its effects on the provision of care concerning the proof of the potential for a permanent adoption in regular care should be provided in the form of valid and reliable data;
- Feasibility of the model approach:
    - Realistic work, time, and milestone plan for the project timeframe;
    - Plausibility of the reachability of case numbers;
    - Description of structures and processes of the project;
    - Appropriateness of the use of resources and financial planning;
    - Appropriateness and necessity of requested funds for the project provision;
- Proportionality of implementation costs and benefits:
    - Expenditures for the realisation of the project, including the evaluation, need to be in a reasonable relation to the envisaged gain of utility.

The healthcare research projects must meet the following criteria to receive funding:

- Improvement of healthcare:
    - Concrete improvement of the quality of care and/or care efficiency, the remedy of care shortcomings within the provisions of the statutory health insurance, and particular proximity to the patient care practice;
- Qualification and previous experience of the applicant:
    - Relevant experience and past projects in care research or the specific research question to be processed (needs to be verified by publications);
    - Involvement of partners from sciences and care practice in the writing of the project description;
- Methodological and scientific quality of the project planning:
    - Competencies and capacities;
    - Consideration of national and international available state of research;
    - Multicenter studies: functioning organisation structures (Project management and measures for quality assurance);
- Utilisation potential:
    - Transfer of the results/strategies for a sustainable implementation;
    - Utilisation for the analysis and/or the improvement of health care for the insured, the further development of clinical practice, and/or structural and organisational improvements;

  - Everything needs to be addressed in the concept of the requested project and described on the structural and processual level;
- Feasibility of the project in the given timeframe:
  - Realistic work, time, and milestone plan for the project timeframe;
  - Plausibility of the reachability of case numbers;
  - Description of structures and processes of the project;
  - Appropriateness of the resource and financial planning;
  - Appropriateness and necessity of requested funds for the project provision;
- Additional funding criteria: relevance:
  - The requested funding project must address a relevant question for the care provisions within statutory health insurance. The significance of the problem needs to be plausible and demonstrated.

Applicant

All persons, legal entities, or any partnerships can apply (link).

There is a formal tender application process for which eligible applicants can apply. All applicants should submit their proposals to DLR Projektträger, which is the tender agent to which all applicants submit their applications and can clarify potential questions during their application process.

For new models of care, eligible projects require collaboration with at least one sickness fund. For healthcare research projects, all parties can apply.

Stakeholders involved

Stakeholder	Role
Federal Joint Committee (G-BA)	Founded the Innovation Fund
Federal Insurance Office (Bundesversicherungsamt)	Manages the Innovation Fund
The Innovation Committee	The steering body of the Innovation Fund. It stipulates the funding announcement and the funding priorities, defines the criteria for funding, and conducts calls for expression of interest based on the funding announcement Finally, it decides on submitted applications; decisions are taken with a majority of seven votes (out of 11 possible)
The Expert Advisory Board	Conducts rapid assessments of received applications for funding and makes final recommendations on funding decisions
Applicant	Submits the application and provides necessary data

Role of the industry

The applications are made by healthcare facilities (hospitals, medical centres, medical universities, etc.). The industry has no direct role in the application or selection process.

Clinical and economic requirements for the scheme

There are no specific clinical or economic requirements to receive a grant from the Innovation Fund. However, the projects must fulfil the abovementioned criteria.

Statistics about the scheme

In August 2022, the G-BA published a report in which the past activities (2016 - August 2022) of the Innovation Fund were evaluated. The statistics below are provided as of July 1, 2022.

Project applications and approvals for new models of care (2016-2020)

Decision date	Requests received	Requests approved	Requests formally excluded	Approval rate	Requested funding (€ mln.)	Approved funding (€ mln.)	Approved funding rate
Oct 2016	120	29	5	24.2%	868	210.7	24.3%
Mar 2017	107	26	11	24.3%	485	111.6	23%
Oct 2017	69	26	7	37.7%	260	101.1	38.9%
Oct 2018	93	38	2	40.9%	439.8	187.6	42.7%
Oct 2019	89	31	N/A	34.8%	499.9	167.9	33.6%
Dec 2020	73	28	N/A	38.4%	421.8	147.6	35%

Project applications and approvals for new models of care (2021-2022)

Decision date	Ideas received	Complete applications received	Applications approved	Approval rate	Approved funding (€ mln.)
Dec 2021	136	33	17	51.5% (of complete applications)	130.2

Decision date	Ideas received	Complete applications received	Applications approved	Approval rate	Approved funding (€ mln.)
End of Q4 2022	123	30	End of Q4 2022	End of Q4 2022	End of Q4 2022
End of Q4 2023	114	End of Q4 2022	End of Q4 2023	End of Q4 2023	End of Q4 2023

Since June 2020, the funding process for new models of care has changed (described in the overview section above). That is why the structures of the two tables (for 2016-2020 and 2021-2022) differ.

Project applications for new models of care per topic (2016-2022)

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ mln.)	Average funding per project (€ mln.)
Oct 2016	T1: Care models in structurally weak or rural areas	12	4	33%	36	9
	T2: Model projects on drug therapy and drug therapy safety	17	4	24%	43	11
	T3: Care models using telemedicine, telematics, and eHealth	34	6	18%	41	7
	T4: Care models for particular patient groups – Elderly	8	1	25%	65	7
	T4: Children and adolescents	10	4			
	T4: People with mental illnesses	10	2			
	T4: Rare diseases	7	1			
	T4: People in need of constant care	5	2			
	Open topics	17	5	29%	26	5
Mar 2017	T1: Models with delegation and substitution of services	19	4	21%	8	2
	T2: Establishment and development of geriatric care	20	4	20%	21	5

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ mln.)	Average funding per project (€ mln.)
	T3: Improving communication with patients and promoting health literacy	31	9	29%	42	5
	T4: Care models for people with disabilities	10	4	40%	7	2
	Open topics	27	5	19%	34	7
Oct 2017	Open topics	69	26	38%	101	4
Oct 2018	T1: Social Welfare Services Models	13	9	69%	38	4
	T2: Cross-disease care models	5	1	20%	6	6
	T3: Care models for specific disease groups	39	15	38%	71	5
	T4: Care for vulnerable people groups	12	4	33%	25	6
	T5: Care models with comprehensive and measurable results and process responsibility	5	2	40%	7	4
	T6: Models for the further development of supply structures and processes	19	7	37%	40	6
Oct 2019	T1: Forms of care for the further development of a sector-independent care	14	5	36%	27	5
	T2: Innovative models to strengthen regional health care	8	4	50%	17	4
	T3: Telemedical cooperation networks of inpatient and outpatient facilities	12	7	58%	41	6
	T4: Care models using the telematics infrastructure	2	0	0%	0	0
	Open topics	53	15	28%	82	5

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ mln.)	Average funding per project (€ mln.)
December 2020	T1: Geriatric medicine - new ways and structures for future care	7	3	43%	14.1	4.7
	T2: Innovative approaches for cooperation between the levels of care for structurally weak regions	5	1	20%	2.5	2.5
	T3: Digital transformation solutions for the further development of care	28	15	54%	91.8	6.1
	T4: Innovative prevention approaches for people with disabilities	5	2	40%	7.5	3.8
	Open topics	28	7	25%	31	4.4
Dec 2021	T1: Further development of care structures and care processes	67	5	7.5%	36	7.2
	T2: Care models for regions with special structural requirements	10	2	20%	10.2	5.1
	T3: Integration and networking of rehabilitation measures to increase the GKV services treatment success	10	2	20%	10.9	5.5
	T4: Care models for patient pathways	15	5	33.3%	48.1	9.6
	T5: Data-based care models for people with chronic diseases in outpatient care	10	2	20%	11.2	5.6
	Open topics	24	1	4.2%	13.6	13.6
Q4 2022	T1: Further development of care through digitization	25	Decisions will be made during the fourth quarter of 2022			

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ mln.)	Average funding per project (€ mln.)
	T2: Interdisciplinary or cross-sectoral care networks and care pathways	40				
	T3: Psychotherapeutic care for vulnerable groups	15				
	T4: Prevention and care in case of serious mental illnesses	7				
	T5: Lessons from the Covid-19 pandemic for the further development of care	5				
	T6: A good start in life with networked care	12				
	Open topics	19				
Total (2016-Dec 15, 2021)		687	195	30%	1054.9	5.5

Approved proposals for new models of care in 2021 (T4 and T5 only) are presented in the table below.

Title of the project	Link	Technology group
T4: Care models for patient pathways		
eRIKA - ePrescription as an element of interprofessional care paths for continuous abbreviated mental test score (AMTS)	Link	E-health
MeMäF - Improving women's health with a digitally supported care model for girls and young women with menstrual pain	Link	Obstetrics and gynaecology
KoCoN - IT-supported cross-sectoral patient paths for the care of children with complex chronic neurological diseases	Link	E-health
Stay@HomeTreat@Home - Development of a telemedically supported transsectoral cooperation network from neighbourhood help to emergency care for ambulatory patients in need of care	Link	E-health
EliPfad - Personalized, interdisciplinary patient path for cross-sectoral care of multimorbid patients with telemedical monitoring	Link	E-health
T5: Data-based care models for people with chronic diseases in outpatient care		

Title of the project	Link	Technology group
DigIn2Perio - Digitally integrated care for type 2 diabetes mellitus and periodontitis	Link	E-health
smartNTX - Interactive, enhanced decision-making competency for transplantation follow-up care	Link	E-health

Project applications and approvals for health care research (2016-2022)

Decision date	Requests received	Requests approved	Requests formally excluded	Approval rate	Requested funding (€ mln.)	Approved funding (€ mln.)	Approved funding rate
Nov 2016	161	62	2	38.5%	168.5	70	41.5%
Nov 2017	164	54	4	32.9%	247.4	69.4	28.1%
Aug 2018	205	55	5	26.8%	303	70	23.1%
Aug 2019	197	59	N/A	29.9%	293.8	67.8	23.1%
Oct 2020	186	33	N/A	17.7%	247.6	37.3	15.1%
Aug 2021	269	52	N/A	19.3%	320.7	44.8	14.0%
Apr 2022*	31	18	N/A	58.1%	14.2	5.1	35.9%
May 2022	161	32	N/A	19.9%	194	38.6	19.9%

*Applications for the topic of clinical guidelines only

Project applications for health care research per topic (2016-2022)

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ Mio)	Average funding per project (€ Mio)
Nov 2016	T1: Quality Assurance and/or Patient Safety in Care	47	15	32%	27.5	1.8
	T2: Instruments for measuring the quality of life (QoL)	8	5	63%	2.9	0.6

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ Mio)	Average funding per project (€ Mio)
	T3: Innovative concepts of patient-oriented care	4	2	50%	2.5	1.2
	T4: Adequacy and/or economic viability of the GKV supply	17	10	59%	7.7	0.8
	T5: Administrative and Bureaucratic Healthcare Requirements	1	1	100%	0.4	0.4
	T6: Use and linking of routine data to improve the supply	27	12	44%	14.4	1.2
	Evaluation of G-BA Guideline: Specialized Outpatient Palliative Care (SAPV)	10	3	33%	3.7	1.2
	Evaluation of selective contracts	9	4	44%	2.6	0.7
	Open topics	38	10	26%	8.8	0.7
Nov 2017	Evaluation of selective contracts	5	4	80%	3.2	0.8
	Open topics	159	50	31%	66.1	1.3
Aug 2018	T1: Special care situations - Care for people with chronic diseases and/or multimorbidity	26	5	19%	4.4	0.9
	T1: Care of geriatric patients	17	5	29%	5.3	1.1
	T1: Care for people with disabilities	7	2	29%	2.7	1.3
	T2: Development of supply structures and concepts - Cooperation of medical and non-medical health workers	11	2	18%	3	1.5
	T2: Models to strengthen health care	3	1	33%	1.2	1.2
	T2: Possibilities of learning algorithms	13	3	23%	3.1	1
	T2: Treatment options after resistance	5	3	60%	6	2

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ Mio)	Average funding per project (€ Mio)
	T3: Patient safety, quality assurance, and promotion - Improving patient safety	23	7	30%	6.7	1
	T3: Sustainable quality promotion	12	3	25%	2.5	0.8
	T3: Demand-oriented care	55	18	33%	27.8	1.5
	T3: Transfer of new scientific knowledge, diffusion of medical progress into the standard care	10	2	20%	3.5	1.7
	T4: Measurement of the quality of results	18	3	17%	3.1	1
	Evaluation of G-BA Guideline: Cancer Screening (KFE-RL)	4	1	25%	0.9	0.9
	Evaluation of selective contracts	1	0	-	-	-
Aug 2019	T1: Strengthening and transparency of quality in nursing care	12	2	17%	3	1
	T2: Improving the access and situation of people with assistance needs and their relatives	14	3	21%	2	0.6
	T3: Preparation and linking of health data from various sources to improve patient care	17	8	47%	10	1.2
	T4: Impact of evidence-based health information for patients on care	23	6	26%	7	1.2
	Evaluation of G-BA Guideline: Outpatient Specialist Medical Care (ASV RL)	11	1	54%	0.8	0.8
	Evaluation of G-BA Guideline: Psychotherapy (PT RL)		4		3	0.7
	Evaluation of selective contracts		1		0.5	0.5

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ Mio)	Average funding per project (€ Mio)
	Open topics	120	34	28%	41	1.2
Oct 2020	T1: Further development of care in essential non-medical settings	23	6	26%	11.5	1.9
	T2: Possibilities for quality assurance of digital care	7	1	14%	0.9	0.9
	T3: Changes in care practice because of digitalisation	20	5	25%	5.7	1.1
	T4: Perspectives and potentials of the use of artificial intelligence in care	17	6	35%	6.3	1.1
	T5: Health services research on guidelines	23	6	26%	3.8	0.6
	Open topics	96	9	9%	9.1	1
Aug 2021	T1 [clinical guidelines]: Healthcare in rare diseases	17	11	64.7%	3.3	0.3
	T2 [clinical guidelines]: Care of people with mental diseases and complex treatment needs	10	8	80%	3	0.4
	T3 [clinical guidelines]: Prevention and treatment of infectious diseases, in particular, to strengthen appropriate antibiotic therapy and contain antimicrobial resistance	4	4	100%	1.2	0.3
	T1: Health services research on findings in dealing with pandemics	15	2	13.3%	2.1	1
	T2: Patient journey in healthcare	37	7	18.9%	8.2	1.1
	T3: Intersectoral and outpatient patient-reported outcome measures (PROMs)/ patient-reported experience measures (PREMs)	23	5	21.7%	8.5	1.7

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ Mio)	Average funding per project (€ Mio)
	T4: Geriatric medicine	22	3	13.6%	4.4	1.5
	T5: Reducing the complexity of administrative tasks in healthcare	3	1	33.3%	1	1
	T6: Strengthen prevention	54	5	9.3%	7.3	1.5
	T7: Hygiene measures in outpatient care	2	0	-	-	-
	T8: Use and trustworthiness of artificial intelligence applications in healthcare	17	2	11.8%	2.7	1.4
	Open topics	65	4	6.2%	3.9	1
Apr 2022*	T1 [clinical guidelines]: Healthcare in rare diseases	7	4	57.1%	0.8	0.2
	T2 [clinical guidelines]: Healthcare in more common diseases, treatment of risk factors for non-communicable diseases, multimorbidity, and improvement of drug therapy safety (AMTS) in healthcare	12	8	66.7%	2.2	0.3
	T3 [clinical guidelines]: Care for target groups with special needs, such as children, young people, the elderly, and/or people in need of care	8	5	62.5%	1.7	0.3
	T4 [clinical guidelines]: Surgical interventions on the skeletal system/locomotor system	4	1	25%	0.4	0.4
May 2022	T1: Patient care and health workers as the subject of health services research	20	3	15%	3.5	1.2
	T2: Evaluation of digital health care	25	8	32%	11.3	1.4

Decision date	Topic	Requests received	Requests approved	Approval rate	Total funding (€ Mio)	Average funding per project (€ Mio)
	T3: Cross-sectoral care for people with chronic diseases or with multimorbidity	19	0	-	-	-
	T4: Gender-specific care	9	1	11.1%	0.6	0.6
	T5: Behavioral approaches to improving healthcare	19	5	26.3%	5.4	1.1
	T6: Focus: Regional health care	9	3	33.3%	5.1	1.7
	T7: Data-driven decision-making to improve healthcare	15	3	20%	4	1.3
	Open topics	45	9	20%	7.6	0.8
Total (2016-May 13, 2022)		1374	365	34%	402.8	1

*Applications for the topic of clinical guidelines only

Approved proposals for health care research topics in 2022 (T2 and T7 only) are presented in the table below.

Title of the project	Link	Technology group
T2: Evaluation of digital health care		
DiGAPS - Digital health applications for mental diseases on the test stand	Link	E-health
Rhe-Turn - E-monitoring to increase the quality of therapy and functional capacity in young rheumatism patients with high disease activity	Link	E-health
Smart-e-Moms - Smartphone-based intervention to reduce postpartum depressive symptoms	Link	E-health
KIDS - AI improves diagnostics in elderly care	Link	E-health
FAIR4Rare - Accompanying evaluation of the development process of an open National Register for Rare Diseases (NARSE)	Link	E-health
ImplementDiGA - Research on the implementation process of digital health applications and their effects on standard care	Link	E-health
FAST - Quickly identify emergencies in the phone queue and route them into a fast track	Link	E-health
DIGAPsy - The implementation of the potential of digital health applications (DiGA) in outpatient care for mental diseases	Link	E-health
T7: Data-driven decision-making to improve healthcare		

Title of the project	Link	Technology group
REPAIR - Recommendation for evidence-based preoperative AI-controlled virtual reduction and osteosynthesis of complex fractures	Link	E-health
Digi-POD - Digitized clinical decision support for the prevention of postoperative delirium	Link	E-health
IntSim-Onko - Integration of clinical and molecular data in precision oncology to develop a similarity-based algorithm for therapy recommendations	Link	E-health

Reference

Web-link to the scheme.

GERMANY: GOVERNMENT CO-FUNDED CLINICAL STUDIES

Title

Government-co-funded clinical studies (Erprobungsstudie), according to the §137e of the German Social Code Book V.

Objective

Co-funded clinical studies were introduced in Germany in 2012 to provide the possibility of obtaining missing evidence about the safety and efficacy of potentially beneficial methods for decision-making processes by the Federal Joint Committee (G-BA). This scheme can be classified as coverage with evidence development program.

Overview

Co-funded clinical studies in Germany are regulated by §137e of the Social Code Book V (SGB V). The framework applies to medical procedures and, theoretically, IVD tests that show a potential medical benefit, but the available evidence is not sufficient to decide on explicit inclusion as a benefit within statutory health insurance.

Co-funded clinical studies can be initiated through direct applications by manufacturers (§137e (7) of SGB V) or in the process of a method evaluation by the Federal Joint Committee (G-BA). The latter can be a consequence of 1) early benefit assessments for innovation funding of high-risk devices (according to §137h SGB V), 2) evaluation of outpatient procedures (according to §135 SGB V), or 3) evaluation of inpatient procedures (according to §137c SGB V).

To directly apply for a co-funded study, an applicant fills in an application form, including the submission of a systematic literature review, an outline of a suggested study, and a letter of intent of cost contribution. The G-BA then determines if the method in question is eligible for a co-funded study and develops a study directive specifying the key characteristics of the study, including indication, intervention and comparison intervention, endpoints, study type, observation period as well as material, personnel, and other requirements. The G-BA collaborates with the Institute for Quality and Efficiency in Healthcare (IQWiG). Before releasing the study directive, the G-BA invites interested parties (experts in medical science and practice, umbrella organizations of medical societies, patient representatives, umbrella organizations of manufacturers of medical products and devices and any manufacturers of medical products that may be affected) to make comments or suggestions.

An independent research institute is contracted via public tender in the next step. The institute is responsible for developing the study protocol, scientific supervision of study conduction, and data analysis. Based on the results of the co-funded study, the G-BA, with the support of IQWiG, decides upon the inclusion or exclusion of the method as a benefit in the statutory health insurance. Evaluation results only apply to the sector (in- or outpatient) defined in the scope of the evidence creation.

While the evidence is collected, a note is made by the G-BA in the Directive for methods delivered in inpatient settings or outpatient settings, specifying the terms of use of the method until a final assessment is made.

In cases where a co-funded study is a consequence of a direct application by a manufacturer, the manufacturer must cover the main costs of the study, including administrative costs as well as costs for the conduction and evaluation of the study. The amount depends on the scope (size and complexity) of the study. The G-BA might take over study costs if the study was initiated through §135 SGB V, §137c SGB V pathway but usually not through §137h SGB V and not if the manufacturer applied directly through §137e SGB V pathway.

Treatment costs are entirely covered by sickness funds. This includes material, medical staff, and infrastructural costs for both the studied intervention and comparative treatment.

In case a co-funded study is initiated through the G-BA during the process of a method evaluation, a cost contribution from manufacturers is only required if the method is essentially based on a specific medical device. The amount of contribution is then determined in each case.

Care settings

In-patient and out-patient specialist settings.

Type of covered technologies

Medical procedures.

Theoretically, in-vitro diagnostic and genetic tests could also be considered in this scheme, although no co-funded studies regarding these technologies were initiated. Two examples of tests that were considered for inclusion in this scheme are molecular gene expression test to monitor low-risk patients after heart transplantation with regard to acute cellular rejection and non-invasive prenatal diagnostics to determine the risk of fetal trisomy 21 using molecular genetic tests).

Inclusion criteria

Methods need to fulfil the following criteria to qualify for evidence creation through a co-sponsored study:

- The method is expected to be less complex, less invasive, have fewer side effects than existing methods, optimise the current treatment or make it more efficient in any other way;
- Sufficient scientific evidence exists as a basis to plan a study that will create significant outcomes for a subsequent method evaluation and reimbursement decision;
- The method is not included as a service in the outpatient catalogue (EBM) (for outpatient services only).

Applicant

Co-funded clinical studies can be initiated in different ways:

- Directly, through the application by manufacturers (§ 137e (7) SGB V);
- Indirectly, as a consequence of the following processes of method evaluation by the G-BA:
    - Early benefit assessment of high-risk devices (137h SGB V), which is a consequence of the application for innovation funding NUB, which is initiated by hospitals;
    - Introduction of a new procedure code into the outpatient catalogue, EBM (§ 135 SGB V), which is initiated by members of the G-BA;
    - Evaluation of a procedure in the inpatient sector (§ 137c SGB V) initiated by members of the G-BA.

Chapter §137e (7) SGB V represents the only possibility for manufacturers to initiate a co-funded study directly. Hospitals can apply for early benefit assessments (§ 137h SGB V), and only members of the G-BA organisations can initiate method evaluations according to §135 SGB V and §137c SGB V. However, in the latter two cases, the G-BA will decide upon the initiation of a co-funded study, in case there is not enough evidence to make a reimbursement decision.

Stakeholders involved

Stakeholder	Role
Federal Joint Committee (G-BA)	Review of eligibility of a method for a co-funded study, release of study directive, evaluation of newly created evidence
Institute for Quality and Efficiency in Healthcare (IQWiG)	Supports G-BA in reviewing of eligibility of a method for a co-funded study and in the evaluation of newly created evidence
Independent research institute	Creation of a study protocol, conduction, and evaluation of the study
Manufacturer(s)	Financing of the major share of the study costs, the outline of the suggested study (in case of direct application)

In case a co-funded study is initiated directly by a manufacturer, according to §137e (7) SGB V, a suggestion of the key elements of the study is submitted with the application. Key elements are the following: study type, indication, population, sample size, intervention and comparison intervention, endpoints, as well as estimated observation period, and study costs. Medical and scientific evidence should support suggestions.

If a co-funded study is initiated in the process of a method evaluation, the G-BA involves manufacturers, hospitals, and other parties with interest in the method in the development of the study directive and considers scientifically valid suggestions.

Role of the industry

The manufacturer finances the major part of the study costs (if the manufacturer applied directly through §137e (7) SGB V pathway or if the study was initiated as a result of the assessment in line with §137h SGB V) and suggests (in the cases where a co-funded study is initiated through a direct application by a manufacturer) or comments on the scope of the suggested study. In case a co-funded study is induced through the G-BA during the process of a method evaluation, a cost contribution from manufacturers is only required if the method is essentially based on a specific medical device.

Clinical and economic requirements for the scheme

The preconditions for the conduction of a co-funded study are that there is sufficient evidence to indicate a potential benefit of the method and to provide a basis to plan a study, the results of which will allow a final decision about the inclusion of the method. Additionally, the manufacturer must sign an agreement to contribute to the costs of the study conduction before the study directive is released.

To provide conclusive results for the subsequent reimbursement decision by the G-BA, co-funded clinical studies need to meet high-level evidence requirements. The G-BA, therefore, specifies the key parameters of the planned co-funded study:

- Study design (required evidence grade, usually randomised controlled trials; RCT, if possible double-blinded);
- Indication and population (100-500 participants);
- Intervention and comparison intervention;
- Patient-related endpoints;
- Observation period;
- Material, personnel, and other requirements for the quality of the study.

Statistics about the scheme

The full number of applications for co-funded clinical studies is unknown. Assessments of eligibility for a co-funded study directly requested by manufacturers are treated as fully confidential if no potential in the method is seen.

G-BA ordered the initiation of 14 co-funded clinical studies since the inception of the regulation (in 2012) till July 1, 2022 (link) (table below).

Procedure	Decision	Effective	Initiation pathway
Magnetic resonance tomography-guided high-focused ultrasound therapy for the treatment of uterine fibroid	15.12.2016	09.03.2017	137e (7), by manufacturers; outpatient sector
Stem cell transplantation in multiple myeloma	19.01.2017	13.04.2017	137c, by sickness funds; inpatient sector

Procedure	Decision	Effective	Initiation pathway
Transcorneal electrostimulation in retinopathy pigmentosa	20.07.2017	07.10.2017	137e (7); outpatient sector
Measurement and monitoring of pulmonary artery pressure using an implanted sensor to optimise the therapy of NYHA III heart failure	19.10.2017	13.01.2018	137e (7); outpatient sector
Liposuction for the treatment of lipedema	18.01.2018	10.04.2018	137e (7); outpatient sector
Tonsillotomy for the treatment of recurrent acute tonsillitis	20.09.2018	14.12.2018	135, outpatient sector; 137c; inpatient sector; by patients' representatives
Active knee movement splints for home self-application as part of the treatment of ruptures of the anterior cruciate ligament	05.09.2019	05.12.2019	135, outpatient sector; 137c, inpatient sector
Pulsating electromagnetic fields in the case of bone healing disorders of the long tubular bones	05.09.2019	07.12.2019	137e (7); outpatient sector
Amyloid positron emission tomography in dementia of unknown aetiology	06.02.2020	03.06.2020	137e (7); outpatient sector
Bronchoscopic lung volume reduction in severe pulmonary emphysema by means of thermal ablation	17.09.2020	16.12.2020	137c, by sickness funds; inpatient sector
Coronary lithoplasty in coronary artery disease	03.02.2022	21.04.2022	The assessment in line with 137h was performed. Benefits were not established. A further testing procedure was offered 135, outpatient sector; 137c, inpatient sector
Microvascular reperfusion of myocardial tissue using intracoronary hyperoxemic therapy (SSO2 therapy) after primary percutaneous	20.02.2022	14.04.2022	The assessment in line with 137h was performed. Benefits were not established. A further testing procedure was offered

Procedure	Decision	Effective	Initiation pathway
coronary intervention in acute anterior wall myocardial infarction			135, outpatient sector; 137c, inpatient sector
High-flow therapy in chronic obstructive pulmonary disease (COPD) and chronic respiratory failure type I	17.02.2022	20.05.2022	135, outpatient sector
High-flow therapy in chronic obstructive pulmonary disease (COPD) and chronic respiratory failure type II	17.02.2022	20.05.2022	135, outpatient sector

Furthermore, it remains unknown whether the studies were not initiated because the methods showed no potential benefit, the manufacturers were unwilling to contribute to costs, or the relevant studies were already underway, making the creation of further evidence redundant.

Not every order by the G-BA resulted in the actual initiation of a co-funded study. From 14 G-BA orders to initiate studies, only eight studies were initiated as of July 01, 2022.

The overview (link) of initiated (in preparation) and ongoing co-funded clinical studies since the introduction of the scheme is provided in the table below (eight in total as of July 01, 2022).

Study title	Independent research institute	Commissioned	Status
AlloRelapseMMStudy - Allogeneic stem cell transplantation in multiple myeloma	University Hospital Hamburg-Eppendorf	04.12.2020	Study in preparation
CAMOped - Active movement splint for self-use at home for ruptures of the anterior cruciate ligament	Medico-academic Consultings (MEDIACC) GmbH	NA, commissioned by the manufacturer	Study ongoing since 08.06.2020
ENABLE - Patient-related and care-related benefits of amyloid PET imaging	German Centre for Neurodegenerative Diseases (DZNE)	02.02.2022	Study in preparation
LIPLEG – Liposuction for lipoedema in stages I, II or III	Clinical Trail Centre Cologne (ZKS)	18.04.2019	Study ongoing since 08.02.2021

Study title	Independent research institute	Commissioned	Status
MARGI-T – Magnetic resonance imaging guided highly focused ultrasound therapy for uterine fibroids	Institute of Clinical Cancer Research (IKF) in Frankfurt am Main	07.11.2018	Study ongoing since 15.07.2020
PASSPORT-HF – Monitoring of pulmonary artery pressure in heart failure	Foundation Institute for Myocardial Infarction Research (IHF) in Ludwigshafen	18.04.2019	Study ongoing since 02.10.2020
TES-RP – Transcorneal electrostimulation in retinopathy pigmentosa	University Hospital Tübingen	16.07.2020	Study ongoing since 01.05.2021
TOTO - Tonsillectomy versus tonsillotomy in recurrent acute tonsillitis	Jena University Hospital	19.12.2019	Study ongoing since 03.11.2020

Reference

Web-link to the scheme.

GERMANY: NEW EXAMINATION AND TREATMENT METHODS (NUB)

Title

New examination and treatment methods (Neue Untersuchungs- und Behandlungsmethoden; NUB).

Objective

New examination and treatment methods (NUB) framework was introduced to incentivise the use of innovative technologies while cost data is collected and analysed before the technology is included in the DRG system. The scheme is classified as an unconditional innovation payment scheme.

Overview

The NUB innovation funding scheme was introduced in 2005, and it provides a temporary payment mechanism to bridge the gap until the new device or procedure obtains regular reimbursement via the DRG system. This temporary payment helps generate the missing case-mix data, which is required for setting an appropriate DRG tariff or creating an add-on payment (ZE).

Each hospital that wants to utilise the NUB funding must apply individually to the Institute for Hospital Remuneration System (InEK). The selection of technologies is made by InEK according to the inclusion criteria (described below). The InEK publishes the results of the NUB assessment as one of the four possible statuses described in the table below:

#	Status	Implication of status
1	NUB criteria fulfilled	The method fulfils the requirements for NUB funding. Hospitals that applied can step into negotiations about reimbursement with the Sickness Funds. InEK further examines whether the method can be adapted under the DRG framework
2	NUB criteria not fulfilled	The NUB application does not fulfil the requirements. The hospital cannot negotiate reimbursement with Sickness Funds. Products that have received this status have rarely received category "1" later
3	Not processed by InEK	InEK did not have time to review the application. The hospital may negotiate reimbursement with Sickness Funds and agree on a regional level. This has not occurred since 2005
4	Not plausible or not comprehensive application	InEK does not have sufficient information to decide on the proposal. The hospital may negotiate reimbursement with interested Sickness Funds. An indication to apply in the following year

A positive decision (status 1) by InEK does not indicate that the additional innovation (NUB) funding is actually granted. Rather, it grants applying hospitals permission to negotiate with local sickness funds. Each hospital must negotiate with local sickness funds, and NUB funding will only be available

to hospitals that negotiated successfully. The financial amount of NUB funding is not determined by InEK but is defined through negotiations between hospitals and sickness funds. Each NUB funding agreement is only valid for one year but can be renewed. Renewals are not possible indefinitely, but usually, NUB payment is renewed for several years.

Hospitals can apply for NUB innovation funding via a standardized form on InEK's website by October 31st of each year. InEK releases its decision about the NUB status on January 31st. Negotiations between hospitals and sickness funds start in February. NUB funding can be granted upon successful negotiations between individual hospitals and local sickness funds.

A specific NUB-related requirement exists for so-called "high-risk medical products" (highly invasive products of classes IIb or III and active implants). Since 2016, these procedures, which are submitted for NUB for the first time, must undergo the early benefit assessment by the Federal Joint Committee (G-BA) to obtain innovation funding (regulated in §137h of the Social Code Book V; SGB V). The assessment process is performed by the Institute for Quality and Efficiency in Healthcare (IQWiG) using the HTA methodology. The hospital making the first application for such a procedure must send additional information to the G-BA, which assesses it with support from IQWiG. If existing scientific evidence is insufficient, the G-BA might order the initiation of a clinical study co-sponsored by the G-BA and the manufacturer or even explicitly exclude the technology from reimbursement within the statutory health insurance.

According to §137h, paragraph 6, of SGB V, manufacturers can request a consultation with the G-BA to confirm whether their product will be eligible for the early benefit assessment. As of July 2022, this possibility has been used 33 times, and in 24 cases, the procedure/technology in question was not eligible for the early benefit assessment framework. In nine cases, procedure/technology was eligible, and in three cases, consultations were still ongoing in July 2022.

Care settings

In-patient settings.

Type of covered technologies

Medical procedures, medical devices, and pharmaceuticals.

Potentially, in-vitro diagnostics tests could also be eligible for the scheme but usually do not receive NUB. Some examples of the tests that were considered but did not receive NUB are molecular pathological diagnostics in malignant neoplasms of the lungs and BRCA diagnostics in ovarian carcinoma, fallopian tube carcinoma, primary peritoneal carcinoma or prostate carcinoma.

Inclusion criteria

The InEK considers the following criteria when evaluating the eligibility of a method for NUB funding:

- The method is a real innovation, and it is new to the German market (i.e., in use for a maximum of four years at the time of first application);
- The hospital's area of expertise includes the relevant patient group;
- The method causes significant extra costs (personnel and material costs; more than one standard deviation of the target DRG) and affects the cost structure of the relevant procedure and the overall cost structure of the hospital;
- The method is currently not covered by an existing DRG.

In relatively rare cases, medical procedures with the use of a high-risk device will trigger an early benefit assessment by the G-BA. This happens if the following criteria are fulfilled:

- The method is based on the use of a "high-risk medical device";
- The method presents a "new theoretic-scientific concept";
- It is the first time a hospital has applied for NUB funding for the method and indication;
- The requesting hospital meets the legal submission requirements.

Applicant

Hospitals make applications for inclusion in the NUB scheme.

Also, the dedicated hospital makes an application in relation to the early benefit assessment (§137h of SGB V) process. However, in the early benefit assessment process, the manufacturer must compile chapters IIIA (information on medical device and provision of available evidence) and IIIB (declaration of agreement between the hospital and the manufacturer) of the application form and provide them to the submitting hospital.

Role of the industry

The industry has no direct role in the NUB application process.

If the method is subject to early benefit assessment, the manufacturer must compile chapters IIIA (information on medical device and provision of available evidence) and IIIB (declaration of agreement between the hospital and the manufacturer) of the application form and provide them to the submitting hospital.

Stakeholders involved

Stakeholder	Role
Institute for Hospital Remuneration System (InEK)	Provision of the application form, collection, and review of applications, the decision about eligibility for NUB funding, monitoring of NUB utilisation
Federal Joint Committee (G-BA)	Performs benefit assessment for methods with the use of invasive devices It also provides consultation services to confirm the eligibility of the method for early benefit assessment

Stakeholder	Role
Institute for Quality and Efficiency in Healthcare (IQWiG)	Producing health technology assessments (HTA) for methods with the use of highly invasive devices on request by the G-BA
Individual Sickness Funds	Acceptance of innovation funding for individual technologies

Clinical and economic requirements for the scheme

No particular economic and clinical requirements exist for inclusion in the NUB innovation funding scheme.

However, in some cases, a method with the use of a high-risk device will trigger an early benefit assessment by the G-BA. The goal of this process is to demonstrate clinical benefit, as well as safety, using the evidence submitted. The applicant must provide evidence that will support the assessment.

In this case, the results of the studies, with their defined endpoints, must be provided and explained clearly. A high level of evidence (one or more RCTs) is required for a successful outcome of the early benefit assessment.

To obtain status 1 (benefit proven), the following criteria must be met:

- The benefit of a method must be verified by qualitatively appropriate documents of high evidence grade (systematic reviews of RCTs, RCTs, and other experimental studies);
- Transferability to actual medical care situation (real-life relevance);
- High quality of planning, performing, and evaluation of the evidence documents and consistency of the results;
- In the assessment of patient outcomes, potential confounders (e.g. age, gender) should be taken into account, and measures should be taken to prevent their impact on the study results;
- In rare diseases or diseases without treatment alternatives, an appraisal of benefits and harms is performed. More extensive documentation and reasoning must be presented as to why the medical benefit can be considered proven.

To obtain status 2 (potential benefit), the following evidence is required:

- RCTs, including small-scale pilot RCTs, short-term RCTs, or RCTs with surrogate endpoints only;
- Non-randomised comparative studies;
- Indirect comparisons between case series or comparisons against other credible safety and efficacy benchmarks.

A potential benefit of a non-invasive technology compared to an invasive one is accepted by IQWiG without data, but comparative treatment effects still need to be presented to allow judgment on the overall benefit-risk ratio.

In the case of ongoing studies of high quality (e.g., high-quality RCTs), the G-BA might prolong the time to the final decision, considering the cost of a co-funded study.

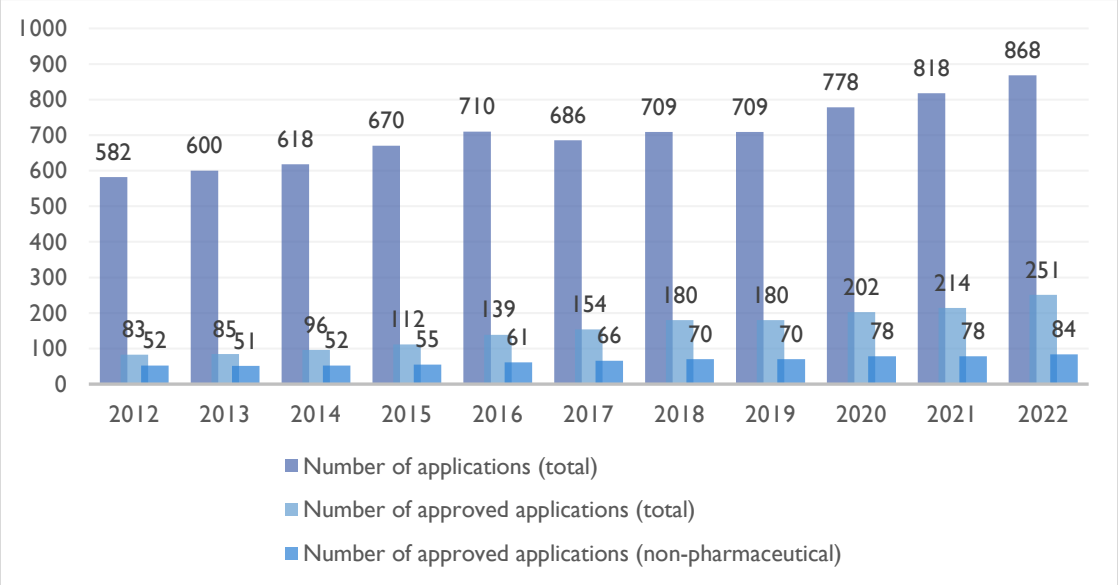
The following situations typically lead to status 3 (a benefit not proven):

- The method generally did not meet the requirements mentioned previously;
- The method is proven not effective or even harmful;
- Poor study design with serious limitations;
- Missing high-grade evidence documents or, in case of rare diseases, lower evidence with little or no potential harm to the patient.

Statistics about the scheme

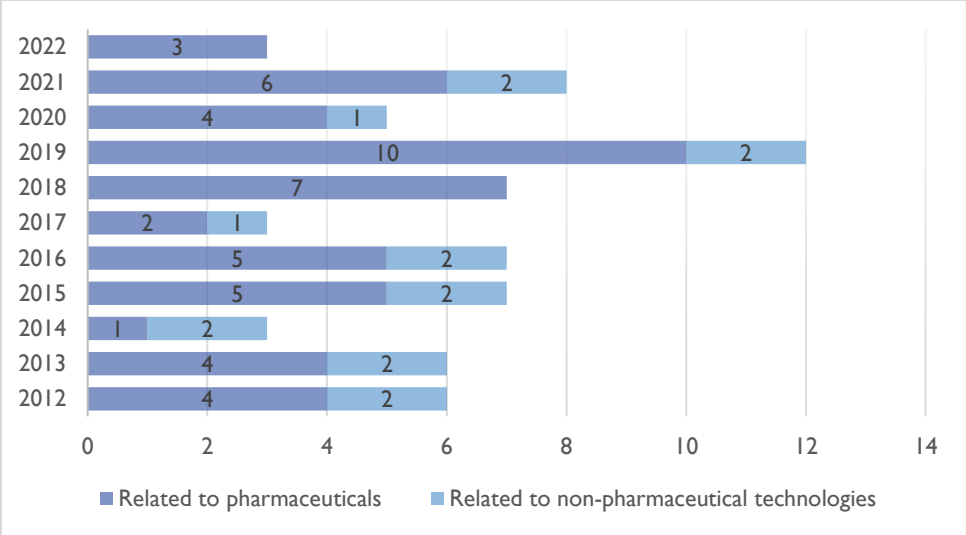
Historical trends

The figure below shows the number of total applications for NUB innovation funding in recent years, as well as the number of approved applications (all types of applications).



The number of approved applications in 2012-2022. Source: MTRC internal knowledge

NUB funding aims to provide temporary coverage for innovative procedures while cost data is collected. Based on the data, procedures are then permanently integrated into the German DRG system. From 2012 to 2022, a total of 61 NUB-funded procedures were incorporated into the DRG system. In total, nine of them (15%) were integrated through the creation of novel DRGs, and 52 (85%) were assigned an add-on reimbursement (ZE) category (allocated to an existing ZE category, or a new ZE category was created). The figure below shows how many of the procedures that were integrated into the system each year were related to drugs or medical technologies, respectively.



The table below represents the breakdown of statistics of NUB applications in the period 2019-2022.

Category	2019	2020	2021	2022
Number of total applications (drugs and devices)	60,185	60,970	75,579	84,041
Number of technologies applied for (drugs and devices)	709	778	818	868
Number of technologies applied for (devices only, % of the total applications)	445 (74%)	552 (71%)	465 (56.8%)	483 (55.6%)
Number of technologies that received status I (drugs and devices)	180	202	214	251
Number of technologies that received status I (devices only, % of the total approved applications)	70 (38.8%)	78 (38.6%)	78 (36.4%)	84 (33.5%)

The table below shows the distribution of technologies selected (status I, and status I differentiated, depending on the indications) for NUB funding by type of technology for the 2019-2022 period.

Technology group	2019		2020		2021		2022	
	Number	%	Number	%	Number	%	Number	%
Cardiovascular	19	21%	21	20%	23	21.9%	22	19.8%
Peripheral vascular	13	14%	16	15%	16	15.2%	16	14.4%
Obstetrics and Gynecology	8	9%	8	7.5%	8	7.6%	8	7.2%
Neurovascular	7	8%	8	7.5%	8	7.6%	8	7.2%

Technology group	2019		2020		2021		2022	
	Number	%	Number	%	Number	%	Number	%
ENT	6	7%	6	6%	7	6.7%	7	6.3%
Radionuclide therapy	7	8%	7	7%	7	6.7%	8	7.2%
Cell therapy	4	4%	5	5%	6	5.7%	6	5.4%
Ophthalmology	4	4%	6	6%	6	5.7%	8	7.2%
Neuromodulation	4	4%	5	5%	4	3.8%	6	5.4%
Orthopaedics	3	3%	4	4%	4	3.8%	4	3.6%
Surgical procedures	4	4%	4	4%	4	3.8%	4	3.6%
Spine	3	3%	3	3%	3	2.9%	3	2.7%
Extracorporeal treatments	2	2%	2	2%	2	1.9%	2	1.8%
Gastrointestinal	2	2%	2	2%	2	1.9%	3	2.7%
Dermatology	1	1%	1	1%	1	1%	1	0.9%
Drug delivery	0	0%	1	1%	1	1%	1	0.9%
Endoscopy	1	1%	2	2%	1	1%	2	1.8%
Men's health	1	1%	1	1%	1	1%	0	0%
Radiotherapy	2	2%	2	2%	1	1%	1	0.9%
Pulmonary and airways	1	1%	1	1%	0	0%	0	0%
Total	**92**	**100%**	**105**	**100%**	**105**	**100%**	**111**	**100%**

2022 statistics

A total of 84,041 requests for NUB funding in 2022, representing 868 unique technologies (drugs, medical devices, in-vitro diagnostics tests, and medical procedures), were submitted to InEK in the autumn of 2021. Positive status was given to 251 (29%) applications, including 84 (9.7% of all applications and 33.5% of all approved technologies) medical devices and medical procedures. Hospitals that sent a request for these technologies had the ability to negotiate innovation funding with sickness funds in 2022.

The complete overview of 2022 NUB applications is available on InEK's website.

List of technologies approved for innovation payment in 2022

In total, 84 procedures fulfilled the criteria for NUB funding and received status 1 in January 2022 (77 of them received innovation payment in the previous year).

Procedure	Number of hospitals	Technology group
Intra-aortic catheter with paracorporeal membrane pump for circulatory support	262	Cardiovascular
Flow-reducing wire mesh in the coronary sinus	257	Cardiovascular
Transcatheter implantation of an interatrial shunt device for the treatment of heart failure	227	Cardiovascular
Percutaneous transluminal insertion of an atrial septal implant for the treatment of heart failure	221	Cardiovascular
Endovascular mitral valve annuloplasty with an annuloplasty band	129	Cardiovascular
Transapical mitral valve reconstruction via implantation of neochordae (polytetrafluoroethylene, PTFE)	128	Cardiovascular
Minimally invasive left ventricle reconstruction with a myocardial anchoring system	105	Cardiovascular
Intra-aortic balloon occlusion with extracorporeal circulation	102	Cardiovascular
The wireless cardiac pacing system of the left ventricle for cardiac resynchronization therapy	100	Cardiovascular
Catheter-based implant for the treatment of left ventricular heart failure	85	Cardiovascular
Percutaneous transluminal implantation of an interatrial shunt for the treatment of heart failure with preserved or reduced left ventricular ejection fraction	75	Cardiovascular
Implantation of the heart valve that grows with the patient	69	Cardiovascular
Endovascular implantation of a stent-graft with valve element in tricuspid valve insufficiency	66	Cardiovascular
Apicoaortic valve-bearing conduit	21	Cardiovascular
Endovascular mitral valve annuloplasty with suture anchors	12	Cardiovascular
Telemetrically adjustable pulmonary artery banding	9	Cardiovascular

Procedure	Number of hospitals	Technology group
Percutaneous transthoracic tricuspid valve replacement	3	Cardiovascular
Administration of CAR-T cells for the treatment of haematological diseases	140	Cell therapy
Transfer of virus-specific donor immune cells after allogeneic stem cell transplantation	132	Cell therapy
Mesenchymal stem cells	115	Cell therapy
Mesenchymal stem cells in therapy-resistant venous ulcers	23	Cell therapy
Allogeneic hepatocyte transplantation	3	Cell therapy
Gene therapy with autologous CD34+ enriched cells with ARSAGs for the treatment of metachromatic leukodystrophy	1	Cell therapy
Full face transplantation	1	Dermatology
Forming of a sleeve stomach (sleeve resection), endoscopic	56	Endoscopy
Endoscopic thermal ablation of the duodenal mucosa to reduce insulin resistance	18	Endoscopy
Direct acoustic stimulation of the cochlea by a Direct Acoustic Cochlear Implant (DACI)	21	ENT
Acoustic neuroma operation with simultaneous cochlear implantation	12	ENT
Thyroplasty implant with the possibility of postoperative adjustment of vocal fold position	11	ENT
Auditory brainstem implant	6	ENT
Auditory midbrain implant	2	ENT
Implantation of an artificial larynx after total laryngectomy	2	ENT
Endovascular implantation of an extracorporeal centrifugal pump for circulatory support	163	Extracorporeal treatments
Ascites treatment with a fully implantable pump	350	Gastrointestinal
Insertion of a colorectal bypass system to protect the anastomosis	29	Gastrointestinal
Focal photodynamic therapy with padeliporfin for the treatment of localized prostate cancer	151	Men's health
Implantation of a gastric pacemaker	203	Neuromodulation

Procedure	Number of hospitals	Technology group
Extracorporeal neurostimulation system for the peripheral nervous system	196	Neuromodulation
Hemodynamically effective implant for the endovascular treatment of intracranial aneurysms and cervical vessels supplying the brain	252	Neurovascular
Intraaneurysmal hemodynamically effective implant for the endovascular treatment of intracranial aneurysms	240	Neurovascular
Removable, ultra-soft microcoils for intracranial therapy of vascular malformations and aneurysms	227	Neurovascular
Fetoscopic drainage therapy	17	Obstetrics and Gynecology
Continuous amnioinfusion using a subcutaneously implanted port system	16	Obstetrics and Gynecology
Fetoscopic tracheal balloon occlusion for diaphragmatic hernia and premature rupture of the bladder	10	Obstetrics and Gynecology
Closure of umbilical cord and intrafetal vessels by percutaneous ultrasound-guided radiofrequency ablation or fetoscopic laser ablation	9	Obstetrics and Gynecology
Fetoscopic opening of narrowed semilunar valves and the foramen ovale	7	Obstetrics and Gynecology
Fetoscopic therapy of fetal supraventricular tachycardia and laryngeal or tracheal occlusion	6	Obstetrics and Gynecology
Uterine occluder system after fetoscopic surgery	4	Obstetrics and Gynecology
Uterus transplantation	2	Obstetrics and Gynecology
Implantation of an intraocular lens with a magnification factor in macular degeneration	11	Ophthalmology
Epiretinal retinal prosthesis	10	Ophthalmology
Boston keratoprosthesis	7	Ophthalmology
Biologically coated keratoprosthesis	5	Ophthalmology
Subretinal active implant	2	Ophthalmology

Procedure	Number of hospitals	Technology group
Implantation of an intraocular lens in patients with macular diseases	1	Ophthalmology
Temporomandibular joint endoprosthesis (total replacement)	122	Orthopaedics
Endo-Exo prosthesis	67	Orthopaedics
Growing endoprostheses	4	Orthopaedics
Joint transplants with thin-layered, fresh, living, allogeneic cartilage or bone material	1	Orthopaedics
Insertion of coated (covered) stents with the bioactive surface for peripheral vessels	535	Peripheral vascular
Covered endoprostheses with the bioactive surface for dialysis shunt revision	373	Peripheral vascular
External stabilization scaffold for anastomosis of an AV shunt as part of shunt surgery	336	Peripheral vascular
Endovascular placement of an internal AV shunt using magnetically guided high-frequency energy	331	Peripheral vascular
Percutaneous caval valve stent placement	104	Peripheral vascular
Endovascular forming of a peripheral AV fistula by direct flow	73	Peripheral vascular
Insertion of coated (covered) stents with the bioactive surface for peripheral and other vessels	89	Peripheral vascular
Insertion of covered stents with the bioactive surface for intra-abdominal, intracranial, or peripheral vessels	69	Peripheral vascular
Replacement of the pulmonary trunk or parts of the aorta with an acellular allograft	64	Peripheral vascular
Thrombectomy of pulmonary vessels using the disc retriever system	63	Peripheral vascular
Insertion of covered stents with the bioactive surface for visceral and supra-aortic vessels	19	Peripheral vascular
PSMA-Actinium-225 (Ac-225) radioligand therapy (RLT)	43	Radionuclide therapy
Radioimmunotherapy with anti-CD19, anti-CD45, and anti-CD66 antibodies	29	Radionuclide therapy

Procedure	Number of hospitals	Technology group
Endoscopic intratumoral injection of phosphorus-32-labeled microparticles under ultrasound guidance in irresectable locally advanced pancreatic tumours	25	Radionuclide therapy
Lutetium-177- or Yttrium-90-pentixafor therapy	10	Radionuclide therapy
Intracavitary radiotherapy with iodine-125	9	Radionuclide therapy
Radionuclide therapy with Lutetium-177-bisphosphonate in bone metastases of prostate cancer	3	Radionuclide therapy
Radionuclide therapy with iodine-131-azetidinylamide in metastatic adrenocortical carcinoma	2	Radionuclide therapy
Radionuclide therapy with Iodine-131-Metomidate	1	Radionuclide therapy
Treatment of children with bladder/prostate/rectum/perineal region rhabdomyosarcoma with organ preserving surgery and interstitial high-dose-rate brachytherapy	1	Radiotherapy
Therapy of scoliosis using magnetically controlled rods	135	Spine
Vertebral bodies growth modulation technique	133	Spine
Scoliosis therapy by self-growing screw-rod system	75	Spine
Combined kidney and stem cell transplantation (from a living donor)	1	Surgical procedures
Treatment of lethal junctional epidermolysis bullosa, Herlitz-type, by transplantation of haploidentical bone marrow and skin of the same donor	1	Surgical procedures

Breakdown of selected technologies in 2022 by type of technology

The table below shows the distribution of non-pharmaceutical technologies selected for NUB payment (obtained status 1) in 2022 by type of technology (including 27 technologies, which received status varying by indication – reviewed in the next section).

The most common technological areas were cardiovascular (19.8%), peripheral vascular (14.4%), neurovascular (7.2%), obstetrics and gynaecology (7.2%), and radionuclide therapy (7.2%).

Technology group	Number	Percentage
Cardiovascular	22	19.8%
Peripheral vascular	16	14.4%
Neurovascular	8	7.2%
Obstetrics and Gynecology	8	7.2%
Ophthalmology	8	7.2%
Radionuclide therapy	8	7.2%
ENT	7	6.3%
Cell therapy	6	5.4%
Neuromodulation	6	5.4%
Orthopaedics	4	3.6%
Surgical procedures	4	3.6%
Spine	3	2.7%
Gastrointestinal	3	2.7%
Extracorporeal treatments	2	1.8%
Endoscopy	2	1.8%
Dermatology	1	0.9%
Drug delivery	1	0.9%
Men's health	1	0.9%
Radiotherapy	1	0.9%
Total	**111**	**100%**

List of selected technologies with NUB status that differs depending on the indication in 2022

In total, 27 procedures received differentiated NUB statuses depending on indications in 2022 (24 of them received innovation funding in the previous year).

Procedure	Status	Indications	Number of hospitals	Technology group
Ablation and event recorder implantation	1 or 2	Status 1: only for cases reimbursed via DRG F50A, without implantation of an event recorder; for all the other cases, status 2 is applicable	343	Cardiovascular

Procedure	Status	Indications	Number of hospitals	Technology group
Coronary self-expanding stent	1 or 2	Status 1: for implantation of 2 and more self-expanding coronary stents; status 2: for implantation of one self-expanding coronary stent	172	Cardiovascular
Antibody-coated drug-eluting coronary stent	1 or 2	Status 1: for the implantation of 2 and more antibody-coated drug-eluting coronary stents; status 2: for the implantation of one antibody-coated drug-eluting coronary stent	116	Cardiovascular
Coronary bifurcation stents	1 or 2	Status 1: for the implantation of 2 and more drug-eluting coronary bifurcation stents; status 2: for the implantation of one non-drug-eluting coronary bifurcation stent or the implantation of one drug-eluting coronary bifurcation stent	82	Cardiovascular
Antibody-coated coronary stent	1 or 2	Status 1: for the implantation of 2 and more antibody-coated coronary stents; status 2: for the implantation of one antibody-coated coronary stent	47	Cardiovascular
Treprostinil application via implantable drug pump in pulmonary artery hypertension	1 or 2	Status 1: for the administration of treprostinil, status 2: for implantable drug pump in pulmonary artery hypertension	29	Drug delivery
Self-expanding, bioresorbable, mometasone furoate-releasing sinus implant	1 or 2	Status 1: for implantation in more than one paranasal sinus; status 2: for implantation in one paranasal sinus	154	ENT
Endovascular implantation of a centrifugal pump for extracorporeal membrane oxygenation	1 or 2	Status 1: if the ZE2022-03 is not applicable; status 2: if the conditions for the ZE2022-03 are met	147	Extracorporeal treatments

Procedure	Status	Indications	Number of hospitals	Technology group
Multivisceral transplantation	1 or 2	Status 1: for all other multivisceral transplants; status 2: for combined transplantation of kidney and pancreas	5	Gastrointestinal
Electrical stimulation system for gastroesophageal reflux disease	1 or 2	Status 1: for cases with a length of stay less than four days; for all the other cases, status 2 is applicable	160	Neuromodulation
Single channel neurostimulator for sacral neuromodulation, rechargeable	1 or 2	Status 1: if the ZE2022-61 or ZE2022-86 are not applicable; status 2: if the conditions for the ZE2022-61 or ZE2022-86 are met	135	Neuromodulation
Microstimulation system for epidural and peripheral neuromodulation for the treatment of chronic, neuropathic pain	1 or 2	Status 1: if no ZE for neurostimulators is applicable; status 2: is the conditions for ZE for neurostimulators are met	87	Neuromodulation
Peripheral microstimulator for sacral neuromodulation	1 or 2	Status 1: if no ZE for neurostimulators is applicable; status 2: is the conditions for ZE for neurostimulators are met	6	Neuromodulation
Bioactive coils	1 or 4	Status 1: for intracranial vessels; status 4: for all the other anatomical areas	269	Neurovascular
Extra-long coils	1 or 4	Status 1: for intracranial vessels; status 4: for all the other anatomical areas	246	Neurovascular
Hybrid coils for intracranial aneurysm treatment	1 or 4	Status 1: for intracranial vessels; status 4: for all the other anatomical areas	215	Neurovascular
Volume coils for aneurysm therapy	1 or 2	Status 1: for intracranial vessels; status 2: for all the other anatomical areas	312	Neurovascular

Procedure	Status	Indications	Number of hospitals	Technology group
Therapy of intracranial vasospasm using controlled, non-occlusive endovascular stent dilation	1 or 2	Status 1: if the ZE152 is not applicable; status 2: if the conditions for the ZE152 are met	218	Neurovascular
Implantation of a Boston keratoprosthesis in combination with the implantation of an intraocular telemetric pressure sensor	1 or 4	Status 1: for the implantation of a Boston Keratoprosthesis; status 4: for the implantation of an intraocular telemetric pressure sensor	4	Ophthalmology
Epiretinal beta-irradiation with intravitreal administration of ranibizumab, aflibercept, or brolucizumab	1 or 4	Status 1: for the intravitreal administration of ranibizumab, aflibercept, and brolucizumab; status 4: for epiretinal beta-irradiation	2	Ophthalmology
Endovascular implantation/repair of a stent prosthesis by endovascular stapler	1 or 2	Status 1: implantation of stent prosthesis was conducted during the previous stay; status 2: implantation of stent prosthesis was performed during the same stay	381	Peripheral vascular
Implantation of a vascular prosthesis with stent insertion during surgical bypass for arteriovenous fistula	1 or 2	Status 1: only in case of arteriovenous shunt surgery in MDC 11 "Disorders of the urinary system"; status 2: for all the other indications or MDCs	385	Peripheral vascular
Hemodynamically effective implant for the endovascular treatment of peripheral aneurysms	1 or 2	Status 1: for other peripheral anatomical areas; status 2: for aorta, if the conditions for the ZE2022-67 are met	185	Peripheral vascular

Procedure	Status	Indications	Number of hospitals	Technology group
Bioresorbable vascular stent	1 or 2	Status 1: for all the other anatomical areas; status 2: for coronary, extremities, and iliac vessels	33	Peripheral vascular
The chimney technique in endovascular aortic aneurysm repair	1 or 2	Status 1: for two or more Chimney stents; status 2: for one Chimney stent	388	Peripheral vascular
AB0-incompatible organ transplantation	1 or 2	Status 1: for AB0-incompatible organ transplantation except for kidney transplantation; status 2: for AB0-incompatible kidney transplantation	7	Surgical procedures
Replacement of vascular graft by vascular homograft	1 or 4	Status 1: for the replacement of an infected vascular graft; status 4: for other indications	77	Surgical procedures

Consultations with the G-BA concerning the eligibility of technologies for early benefit assessments in line with §137h of SGB V

Manufacturers of medical technologies can consult G-BA about the eligibility of their new method for early benefit assessment before the first-time submission to NUB (link).

In total, as of July 1, 2022, 33 consultations with G-BA were performed concerning the early benefit assessment for medical technologies and procedures in line with § 137h SGB V. As of July 1, 2022, consultations for three more methods were ongoing.

Seven consultations were performed in 2017, three in 2018, six in 2020, fourteen in 2021, and three in 2022.

In twenty-four cases (72.7%), the medical technology/procedure was not subject to early benefit assessment. In nine cases (27.3%), the medical technology/procedure was found suitable for early benefit assessment.

The list of consultations performed by G-BA concerning the eligibility of medical technology for early benefit assessment in line with § 137h SGB V (as of July 2022) is provided in the table below. In case the same method was assessed several times, the final decision is provided in the table.

Title	Device brand	Year	Technology group	Type of recommendation
Magnetic resonance imaging-guided transurethral ultrasound	NA	2017	Men's health	The consultation was performed. Early

Title	Device brand	Year	Technology group	Type of recommendation
ablation of prostate tissue in patients with localized prostate cancer				benefit assessment is not needed
Electrical stimulation of the peripheral nervous system by a partially implantable neurostimulation system in chronic pain	NA	2017	Neuromodulation	The consultation was performed. Early benefit assessment is not needed
Transcervical intrauterine ultrasound-guided radiofrequency ablation of uterine fibroids	Sonata® System (Gynesonics Inc)	2017	Obstetrics and gynaecology	The consultation was performed. The procedure was found suitable for early benefit assessment
Endovascular minimally invasive deep veins arterialization in peripheral arterial disease and critical limb ischemia	NA	2017	Peripheral vascular	The consultation was performed. Early benefit assessment is not needed
Endovascular femoropopliteal bypass using intravenously implanted stent-grafts in peripheral arterial disease	NA	2017	Peripheral vascular	The consultation was performed. Early benefit assessment is not needed
Use of combined central venous catheter and inferior vena cava filter in critically ill patients at high risk of pulmonary embolism	NA	2017	Peripheral vascular	The consultation was performed. Early benefit assessment is not needed
Targeted lung denervation through catheter ablation in chronic obstructive pulmonary disease	Holaira™ Lung Denervation System (Holaira Inc.)	2017	Pulmonary and Airways	The consultation was performed. The procedure was found suitable for early benefit assessment
Padeliporfin focal vascular targeted photodynamic therapy for the treatment of localized prostate cancer	NA	2018	Men's health	The consultation was performed. Early benefit assessment is not needed
Implantation of removable ultra-soft microcoils for intracranial vascular malformations and aneurysms	NA	2018	Neurovascular	The consultation was performed. Early benefit assessment is not needed
Ultrasound-activated, resorbable implants for	NA	2018	Orthopaedics	The consultation was performed. Early

Title	Device brand	Year	Technology group	Type of recommendation
osteosynthesis in hallux valgus osteotomy				benefit assessment is not needed
Transcatheter mitral valve replacement in mitral valve insufficiency	NA	2020	Cardiovascular	The consultation was performed. Early benefit assessment is not needed
Thyroplasty with adjustment option in glottic insufficiency	NA	2020	ENT	The consultation was performed. Early benefit assessment is not needed
Use of normothermic and pulsatile organ preservation with function monitoring in heart transplantation	NA	2020	Extracorporeal treatments	The consultation was performed. Even though the required conditions were fulfilled, the early benefit assessment was not started
Sacral neuromodulation through an implantable, rechargeable stimulation system for overactive bladder, urinary retention, and faecal incontinence	NA	2020	Neuromodulation	The consultation was performed. Early benefit assessment is not needed
Stimulation of the hypoglossal nerve by a partially implantable stimulation system for obstructive sleep apnea	NA	2020	Neuromodulation	The consultation was performed. Early benefit assessment is not needed
Distraction osteogenesis through internal bone transport with compression in the case of bone defects	NA	2020	Orthopaedics	The consultation was performed. Early benefit assessment is not needed
Coronary lithoplasty in coronary heart disease	Shockwave C2 Coronary Intravascular Lithotripsy (IVL) System (Shockwave Medical Inc.)	2021	Cardiovascular	The consultation was performed. Early benefit assessment is not needed
Endovascular implantation of a stent-graft with integrated valve in tricuspid valve insufficiency	THREE HUNDRED (New Valve Technology GmbH)	2021	Cardiovascular	The consultation was performed. Early benefit assessment is not needed

Title	Device brand	Year	Technology group	Type of recommendation
Microvascular reperfusion of myocardial tissue using intracoronary, hyperoxemic therapy after primary percutaneous coronary intervention in acute anterior wall infarction	TherOx DownStream System (class IIb) and Therox SSO2 Delivery System consisting of TherOx DownStream cartridge (class IIb) and Boston Scientific Impulse angiography catheter (class III) (TherOx Inc.)	2021	Cardiovascular	The consultation was performed. The procedure was found suitable for early benefit assessment
Percutaneously implanted interatrial shunt for the treatment of heart failure	Ventura® Interatrial Shunt System (V-Wave Ltd.)	2021	Cardiovascular	The consultation was performed. Early benefit assessment is not needed
Endovascular implantation of a transcatheter tricuspid valve replacement in tricuspid regurgitation	NA	2021	Cardiovascular	The consultation was performed. Even though the required conditions were fulfilled, the early benefit assessment was not started
Endoscopic duodenal thermal ablation in type 2 diabetes mellitus	REVITA DMR-System (Fractyl Laboratories Inc.)	2021	Endoscopy	The consultation was performed. Early benefit assessment is not needed
Use of normothermic and pulsatile organ preservation with function monitoring in liver transplantation	Organ Care System™ (OCS™) Leber (TransMedics, Inc.)	2021	Extracorporeal treatments	The consultation was performed. Even though the required conditions were fulfilled, the early benefit assessment was not started
Use of normothermic and pulsatile organ preservation with function	NA	2021	Extracorporeal treatments	The consultation was performed. Even though the required

Title	Device brand	Year	Technology group	Type of recommendation
monitoring in lung transplantation				conditions were fulfilled, the early benefit assessment was not started
Drug-coated balloon catheter for the transurethral treatment of urethral strictures	Optilume (Urotronic Inc.)	2021	Nephrology and urology	The consultation was performed. Early benefit assessment is not needed
Transcranial magnetic resonance-guided focused ultrasound (TK-MRgFUS) for the treatment of essential tremor	ExAblate® Model 4000 Type 1.0 (INSIGHTEC Ltd)	2021	Neurology and neurosurgery	The consultation was performed. Early benefit assessment is not needed
Use of a stent retriever for treatment of cerebral arteries vasospasm after subarachnoid haemorrhage	pRELAX (femtos GmbH)	2021	Neurovascular	The consultation was performed. Even though the required conditions were met, the early benefit assessment was not started
Bronchoscopic, navigation system-guided microwave ablation for the treatment of inoperable primary and oligometastatic non-small cell lung cancer	NA	2021	Pulmonary and Airways	The consultation was performed. Even though the required conditions were met, the early benefit assessment was not started
Irreversible electroporation in chronic bronchitis	RheOx™ Technology (Gala Therapeutics Inc.)	2021	Pulmonary and Airways	The consultation was performed. Early benefit assessment is not needed
Ultra-long-term EEG using a subgaleally implanted electrode in epilepsy	NA	2021	Neurology and neurosurgery	The consultation was performed. Early benefit assessment is not needed
3D real-time visualization for navigation during endovascular interventions on the aorta, the aortic branches vessels, and the peripheral arteries	NA	2022	Diagnostic imaging	The consultation was performed. Early benefit assessment is not needed
Implantation of a miniature telescope in stable age-	NA	2022	Ophthalmology	The consultation was performed. Early

Title	Device brand	Year	Technology group	Type of recommendation
related macular degeneration				benefit assessment is not needed
Intracranial tumour resection of high-grade brain tumours using confocal laser endomicroscopy (in vivo) for intraoperative evaluation of tumour margins	NA	2022	Neurology and neurosurgery	The consultation was performed. Early benefit assessment is not needed
Prolonged CPR with the additional use of an extracorporeal heart and lung replacement system with integrated treatment and monitoring modules in cardiac arrest	NA	Ongoing	Intensive care	Not available
Pulmonary thrombectomy using a disc retriever for pulmonary artery embolism	FlowTriever™ (Inari Medical Inc.)	Ongoing	Peripheral vascular	Not available
Use of normothermic and pulsatile organ preservation with function monitoring in liver transplantation	Organ Care System™ (OCS™) Leber (TransMedics, Inc.)	Ongoing	Extracorporeal treatments	Not available

Decisions from early benefit assessments by G-BA in line with §137h SGB V

In total, as of July 1, 2022 (link), fifteen early benefit assessments for medical technologies and procedures were performed in line with §137h of SGB V. Eight decisions were made in 2017, four in 2021, and three in 2022.

In addition, in four cases, the assessment was initiated but terminated as not all conditions of the §137h of SGB V regulation were met (e.g., technology was submitted for NUB earlier):

- External stabilization of an arteriovenous anastomosis using a scaffold in patients with an indication to create a shunt (VasQ, Laminate Medical Technologies Ltd.);
- Endovascular direct insertion of an arteriovenous fistula in patients with indication for hemodialysis (Ellipsys® Vascular Access System, Avenue Medical, Inc.);
- Minimally invasive left ventricular reconstruction using an anchoring system for heart failure (Revivent TC™ Transkatheter Ventricular Enhancement System, BioVentrix, Inc.);

- Transvascular, transcatheter-assisted implantation of an aortic valve for the treatment of aortic valve insufficiency and aortic stenosis (Trilogy™ Heart Valve System, enaValve Technology, Inc.).

Individual policies in line with §137h SGB V (as of July 2022) are listed in the table below.

Title	Device brand	Year	Technology group	Type of recommendation
Ultrasound-guided high-intensity focused ultrasound for the treatment of non-resectable hepatocellular carcinoma	Model JC Focused Ultrasound Tumor Therapeutic System (Chongqing Haifu Medical Technology Co. Ltd.)	2017	Gastrointestinal	The assessment was performed. A potential benefit is determined by G-BA, offered a testing procedure, but then it was cancelled due to the lack of willingness to accept the guidelines
Ultrasound-guided high-intensity focused ultrasound for the treatment of non-resectable malignant neoplasms of the pancreas	Model JC Focused Ultrasound Tumor Therapeutic System (Chongqing Haifu Medical Technology Co. Ltd.)	2017	Gastrointestinal	The assessment was performed. Benefits were not established. Although a further testing procedure was offered, it was cancelled due to the lack of willingness to accept the guidelines
Ultrasound-guided high-intensity focused ultrasound for the treatment of non-resectable secondary malignant neoplasms of the liver and intrahepatic bile ducts	Model JC Focused Ultrasound Tumor Therapeutic System (Chongqing Haifu Medical Technology Co. Ltd.)	2017	Gastrointestinal	The assessment was performed. No benefit was established
Ultrasound-guided high-intensity focused ultrasound for the treatment of endometriosis of the uterus	Model JC Focused Ultrasound Tumor Therapeutic System (Chongqing Haifu Medical Technology Co. Ltd.)	2017	Obstetrics and Gynaecology	The assessment was performed. No benefit was established
Ultrasound-guided high-intensity focused ultrasound for the treatment of uterine leiomyomas	Model JC Focused Ultrasound Tumor Therapeutic System (Chongqing Haifu Medical Technology Co. Ltd.)	2017	Obstetrics and Gynaecology	The assessment was performed. A potential benefit is determined by G-BA, offered a testing procedure, but then it was cancelled due to the lack of willingness to accept the guidelines

Title	Device brand	Year	Technology group	Type of recommendation
Ultrasound-guided high-intensity focused ultrasound for the treatment of non-resectable primary malignant neoplasms of bone and articular cartilage	Model JC Focused Ultrasound Tumor Therapeutic System (Chongqing Haifu Medical Technology Co. Ltd.)	2017	Orthopaedics	The assessment was performed. No benefit was established
Ultrasound-guided high-intensity focused ultrasound for the treatment of non-resectable secondary malignant neoplasms of the bone and bone marrow	Model JC Focused Ultrasound Tumor Therapeutic System (Chongqing Haifu Medical Technology Co. Ltd.)	2017	Orthopaedics	The assessment was performed. No benefit was established
Targeted lung denervation through catheter ablation in chronic obstructive pulmonary disease	Holaira™ Lung Denervation System (Holaira Inc.)	2017	Pulmonary and Airways	The assessment was performed with the inclusion of procedure into Annex II A (with evaluations put on hold due to ongoing or planned studies) of the Directive for treatment methods in hospital settings
Drug-coated balloon catheter for the transurethral treatment of urethral strictures	Optilume (Urotronic Inc.)	2021	Nephrology and urology	The assessment was performed. Benefits were not established. A further testing procedure was offered
Coronary lithoplasty for coronary artery disease	Shockwave C2 Coronary Intravascular Lithotripsy (IVL) System (Shockwave Medical Inc.)	2021	Cardiovascular	The assessment was performed. Benefits were not established. A further testing procedure was offered
Microvascular reperfusion of myocardial tissue using intracoronary, hyperoxemic therapy after primary percutaneous coronary intervention in acute anterior wall infarction	TherOx DownStream System (class IIb) and Therox SSO2 Delivery System consisting of TherOx DownStream cartridge (class IIb) and Boston Scientific Impulse angiography	2021	Cardiovascular	The assessment was performed. Benefits were not established. A further testing procedure was offered

Title	Device brand	Year	Technology group	Type of recommendation
	catheter (class III) (TherOx Inc.)			
Endoscopic duodenal thermal ablation in type 2 diabetes mellitus	REVITA DMR-System (Fractyl Laboratories Inc.)	2021	Endoscopy	The assessment was performed. Benefits were not established. A further testing procedure was offered
Endoscopic injection implantation of 32P microparticles in irresectable, locally advanced pancreatic tumours	OncoSil™-System (OncoSil Medical Ltd.)	2022	Radiotherapy	The assessment was performed. Benefits were not established. A further testing procedure was offered
Transcervical radiofrequency ablation with intrauterine ultrasound guidance in uterine fibroids	Sonata® System (Gynesonics Inc)	2022	Obstetrics and Gynecology	The assessment was performed. Benefits were not established. A further testing procedure was offered
Use of a stent retriever to treat cerebral artery vasospasm after subarachnoid haemorrhage	pRELAX (femtos GmbH)	2022	Neurovascular	The assessment was performed. Benefits were not established. A further testing procedure was offered

Reference

Web-link to the scheme.

GERMANY: PROVISIONAL LISTING OF DIGITAL HEALTH APPLICATIONS

Title

Provisional listing of Digital Health Applications in the Digital Health Applications (DiGA) Directory (Vorläufige Aufnahme in das DiGA-Verzeichnis)

Objective

The Fast-Track Process for digital health applications (DiGA) was introduced for rapid approval, testing, and reimbursement of DiGAs to simplify the implementation of the innovative apps into standard healthcare.

The final listing in DiGA Directory represents a regular (established) reimbursement process for digital applications, and it is outside of the scope of this report. This report focuses only on the provisional listing in the DiGA Directory, which can be considered coverage with the evidence development scheme.

The provisional listing provides a possibility to be included in the Directory for one year (in exceptional cases – for up to two years) with reimbursement available at a price set by the manufacturer (up to the 13th month of inclusion in the Directory). During that period, the manufacturer has to submit study results providing evidence of positive healthcare effects of the digital health application to the BfArM to obtain a final listing in the Directory.

Overview

The Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG) came into effect on December 19, 2019, introducing the "app on prescription" as part of healthcare provided to patients. These applications can be prescribed by physicians and psychotherapists and are reimbursed by sickness funds. Insured persons who can provide their sickness funds with proof of a corresponding indication are also eligible to receive the desired digital health app without a prescription.

The Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) has regulated the details of the application procedure, the requirements for the digital health applications, and the structure of the Directory of reimbursable digital health applications (DiGA Directory) in the Digital Health Applications Regulation (Digitale-Gesundheitsanwendungen-Verordnung, DiGAV).

On June 9, 2021, the Law on Digital Modernization of Healthcare and Nursing (Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz, DVPMG) came into force. Among others, the DVPMG creates the necessary legal requirements and incentives for reimbursement of digital nursing care applications (DiPAs) in the same manner as digital health applications. Digital nursing care applications don't have to be medical devices and, unlike digital health apps, do not require CE marking.

A digital health application must have successfully completed the assessment of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), leading to a listing in the DiGA Directory, established and maintained by BfArM.

The procedure is designed as a fast-track process (see figure): within a three-month period, starting with the filing of the complete application, the BfArM has to assess it. The essence of this assessment is the examination of the manufacturer's statements about the product qualities, from data protection to user-friendliness, and the examination of the evidence of the positive healthcare effect of the digital health application provided by the manufacturer.

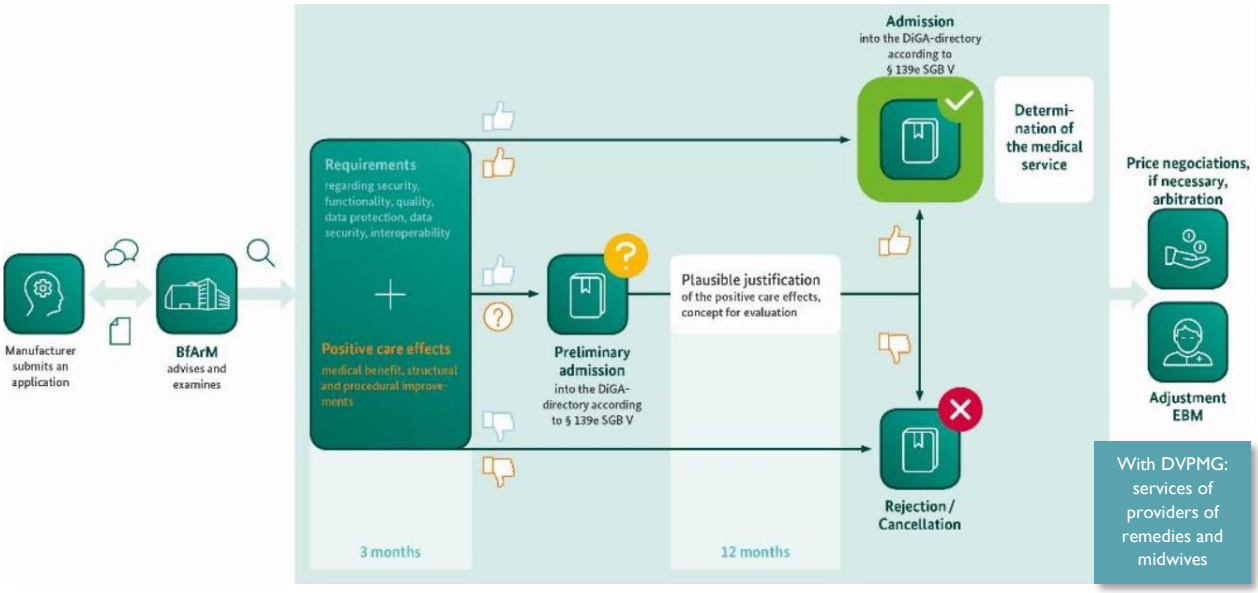


Figure. The sequence of the Fast Track procedure (BfArM). Source of the image: BfArM

Before an application is made, the manufacturer of the digital health application has first to decide whether to apply provisionally or directly for final listing in the Directory. This decision essentially depends on whether the manufacturer can already present a comparative study to prove a positive healthcare effect that meets the requirements of §10 to §12 DiGAV.

Manufacturers who have not yet conducted a suitable study with their digital health application to provide evidence of positive healthcare effect can apply for provisional listing in the Directory. However, the digital health application must already meet all requirements in accordance with §3 to §6 DiGAV (security, functional capability, quality, data protection, and information security) at the time of application.

The provisional listing offers a possibility to be included in the Directory for a one-year trial phase with reimbursement available at a price set by the manufacturer (up to the 13th month of inclusion in the Directory). Once the digital health app is listed in the Directory, it can be prescribed by physicians and psychotherapists and will be reimbursed by the sickness funds.

During the trial phase, the manufacturer has to submit study results providing evidence of positive healthcare effects of the digital health application to the BfArM. The manufacturer can apply for an extension of the trial phase (up to two years) before it expires, justifying why the evidence is not yet available.

At the end of the trial phase, in the case of a positive decision by the BfArM, the health app will obtain a final listing in the Directory; otherwise, it will be removed from the Directory.

Following the final listing of the digital health app in the Directory, the National Association of Statutory Health Insurance Funds (GKV-SV) and the manufacturer negotiate the reimbursement amount.

The prerequisites of the price negotiations are the following:

- An actual daily price for the digital health application both upon inclusion in the DiGA Directory and in the subsequent period is 25% higher than the average price of all digital health applications included in the DiGA Directory;
- The yearly sales threshold for the digital health application exceeds the amount of €750,000, including sales tax.

If there are four or more digital health applications in a group, the group-specific maximum amount is calculated using statistical methods to identify the 80% quantile (80% of the negotiated reimbursement amount).

There is no upper price limit for a digital health application if:

- It is largely intended to support the detection, monitoring, treatment or alleviation of rare diseases;
- It is based on artificial intelligence in terms of its main function;
- The manufacturer asserts another special reason comparable to the ones provided above for an exemption from the application of the upper price limit.

In case no agreement between the GKV-SV and the manufacturer is reached, the reimbursement amount will be set by the Arbitration Board within a period of three months.

The framework is currently going through frequent updates, and it is unclear how the requirements and reimbursement will unfold further on.

Care settings

Out-patient specialist settings and community settings (home care).

Type of covered technologies

Digital health applications.

Inclusion criteria

To be listed in the Directory according to §139e SGB V, a DiGA must meet the following requirements (§3 to §6 of the DiGAV):

- Safety and suitability for use;
- Data protection and information security;
- Quality, especially interoperability.

Manufacturers must demonstrate this to the BfArM with emphasis on the completed checklists provided in appendices 1 and 2 of the DiGAV, as well as the evidence of compliance with regulatory requirements for medical devices.

As a rule, data processing within the EU is allowed. Data processing outside the EU in a so-called third country is permissible when a comparable level of data protection exists in the third country.

Since January 1, 2023, in line with DVPMG, digital health applications should provide the possibility to connect their interface to the personal health record (ePA) of the patient.

The BfArM can request further evidence on individual quality features during the application assessment and check the accuracy of the information. In any case, free access (login data) to the DiGA must be provided to the BfArM (§2 paragraph 4 DiGAV) by the manufacturer.

Applicant

Manufacturers of health apps make the application for inclusion in the scheme.

Stakeholders involved

Stakeholder	Role
Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)	Conducts the consultation appointments with the manufacturers on request, reviews the applications and decides on the inclusion in the Directory, maintains the Directory, and informs the GKV-SV of the need for corresponding price negotiations
Manufacturer	Applies for the inclusion in the Directory, providing the necessary information required for the inclusion of the DiGA in the Directory, provides the study results confirming the positive healthcare effect in a timely manner in the case of provisional listing, negotiates the reimbursement amount with the GKV-SV after final listing in the DiGA Directory (or, if applicable, after the 13th month of the inclusion in the Directory)
National Association of Statutory Health Insurance Funds (Gesetzliche Krankenversicherung-Spitzenverband, GKV-SV)	Negotiates the reimbursement amount with the manufacturer after final listing in the DiGA Directory (or, if applicable, after the 13th month of the inclusion in the Directory)

Role of the industry

The manufacturer applies for inclusion in the Directory, providing the necessary information required for the inclusion of the DiGA in the Directory. In the case of provisional listing, the manufacturer should provide the study results confirming the positive healthcare effect in a timely manner. The manufacturer negotiates the reimbursement amount with the GKV-SV after the final listing in the DiGA Directory (or, if applicable, after the 13th month of the inclusion in the Directory).

Clinical and economic requirements for the scheme

Depending on the research question and the endpoints investigated, results of clinical or epidemiological studies can be presented to prove positive healthcare effects. The prerequisite is that these are quantitative comparative studies and that the methodology is adequate for the chosen object of investigation.

The studies must be conducted in Germany. If, in individual cases, evidence for comparability of the healthcare situation can be provided, studies conducted in whole or in part in countries outside of Germany will also be recognised.

Positive healthcare effects are both medical benefits as well as patient-relevant improvements of structure and processes, which refer directly to the patient and shall be demonstrated by appropriate endpoints.

The medical benefit (medizinischer Nutzen, mN) is defined as patient-relevant effect(s), particularly regarding the improvement of the state of health, the reduction of the duration of a disease, the prolongation of survival or an improvement in the quality of life. The manufacturers claiming a medical benefit for a digital health application must demonstrate that patient-relevant endpoints, in particular morbidity, mortality or quality of life, are positively affected.

The patient-relevant improvements of structure and processes (patientenrelevante Struktur- und Verfahrensverbesserungen, pSVV) are:

- Seen as part of the detection, monitoring, treatment, or alleviation of disease or detection, treatment, alleviation or compensation of injury or disability; and are
- Aimed at supporting the health behaviour of patients or integrating the processes between patients and healthcare providers; and
- Include in particular the areas in which positive healthcare effects (pVE) can be demonstrated:
    - Coordination of treatment procedures;
    - Alignment of treatment with guidelines and recognised standards;
    - Adherence;
    - Facilitating access to care;
    - Patient safety;
    - Health literacy;
    - Patient autonomy;

- Coping with illness-related difficulties in everyday life; or
- Reduction of therapy-related efforts and strains for patients and their relatives.

The digital health application must demonstrate at least one of the medical benefits or patient-relevant improvements of structure and processes.

Statistics and trends about the use of the scheme

In total (as of August 24, 2022), as reported by the BfArM (link), out of 147 applications, 35 (23.8%) were accepted, a negative decision was drawn for 13 (8.8%) applications, 80 (54.4%) applications were withdrawn, and 19 (12.9%) are currently under evaluation. One potential reason for withdrawing the application can be to avoid the publication of a negative decision by authorities.

The first digital health app (Kalmeda) was included in the Directory on September 25, 2020 (provisional listing; final listing since December 18, 2021). As of July 1, 2022, there are 32 DiGAs included in the Directory: 12 (37.5%) health apps in the final listing and 20 (62.5%) health apps in the provisional listing.

Two health apps were excluded from the Directory at the request of the manufacturer: Mika (provisional listing since March 25, 2021; excluded on March 25, 2022) and M-sense Migräne (provisional listing since December 16, 2020; excluded on April 4, 2022).

The digital health applications included in the Directory as of July 1, 2022, are provided in the table below.

Name	Manufacturer	Provisional listing	Final listing	Price, €
CANKADO PRO-React Onco	CANKADO Service GmbH	03.05.2021, extended until 02.05.2023	NR	499.80
Cara Care für Reizdarm	HiDoc Technologies GmbH	26.12.2021, valid until 25.12.2022	NR	718.20
companion patella powered by medi - proved by Dt. Kniegesellschaft	PrehApp GmbH	04.10.2021, valid until 03.10.2022	NR	345.10
deprexis	GAIA AG	NR	20.02.2021	297.50 / 210*
elevida	GAIA AG	NR	15.12.2020	743.75 / 243*
ESYSTA App & Portal – Digitales Diabetesmanagement	Emperra GmbH E-Health Technologies	04.07.2021, extended until 03.10.2022	NR	249.86
HelloBetter Diabetes und Depression	GET.ON Institut für Online	NR	11.12.2021	599

Name	Manufacturer	Provisional listing	Final listing	Price, €
	Gesundheitstrainings GmbH			
HelloBetter Panik	GET.ON Institut für Online Gesundheitstrainings GmbH	NR	03.04.2022	599
HelloBetter ratiopharm chronischer Schmerz	GET.ON Institut für Online Gesundheitstrainings GmbH	18.12.2021, valid until 17.12.2022	NR	599
HelloBetter Stress und Burnout	GET.ON Institut für Online Gesundheitstrainings GmbH	NR	18.10.2021	599
HelloBetter Vaginismus Plus	GET.ON Institut für Online Gesundheitstrainings GmbH	NR	04.02.2022	599
Invirto- Die Therapie gegen Angst	Sympatient GmbH	03.12.2020, extended until 02.09.2022	NR	428.40 / 620*
Kalmeda	mynoise GmbH	25.09.2020	18.12.2021	203.97 / 189*
Kranus Edera	Kranus Health GmbH	18.12.2021	NR	552 / 656.88*
Mawendo	Mawendo GmbH	09.08.2021	NR	119
Meine Tinnitus App - Das digitale Tinnitus Counseling	Sonormed GmbH	06.03.2022	NR	449
Mindable: Panikstörung und Agoraphobie	Mindable Health GmbH	29.04.2021, extended until 28.04.2023	NR	576
neolexon Aphasie	Limedix GmbH	06.02.2022	NR	487.90
NichtraucherHelden-App	NichtraucherHelden GmbH	03.07.2021, extended until 02.07.2023	NR	239 / 329 (first order); 99 / 119 (following orders)*
Novego: Depressionen bewältigen	IVPNetworks GmbH	10.10.2021	NR	249
Oviva Direkt für Adipositas	Oviva AG	03.10.2021	NR	345 / 445

Name	Manufacturer	Provisional listing	Final listing	Price, €
PINK! Coach	PINK gegen Brustkrebs GmbH	27.06.2022	NR	535.50
Rehappy	Rehappy GmbH	29.12.2020, extended until 28.09.2022	NR	299 (without fitness tracker); 449 (with fitness tracker)
Selfapys Online-Kurs bei Depression	Selfapy GmbH	NR	16.12.2020	540
Selfapys Online-Kurs bei Generalisierter Angststörung	Selfapy GmbH	19.06.2021, extended until 18.10.2022	NR	540
Selfapys Online-Kurs bei Panikstörung	Selfapy GmbH	19.06.2021, extended until 18.10.2022	NR	540
Somnio	mementor DE GmbH	NR	22.10.2020	464 / 224.99*
velibra	GAIA AG	NR	01.10.2020	476 / 230*
Vitadio	Vitadio s.r.o. (Czech Republic)	15.04.2022	NR	499.80
Vivira	Vivira Health Lab GmbH	22.10.2020	17.02.2022	239.96
vorvida	GAIA AG	NR	06.05.2021	476
zanadio	aidhere GmbH	22.10.2020, extended until 21.08.2022	NR	499.80

Note. *The price at the inclusion in the Directory / after the price negotiations

The table below demonstrates the distribution of digital health applications (for provisional listing) included in the Directory by disease area. The most common disease areas covered are mental and behavioral disorders, endocrine and metabolic disorders (diabetes, obesity), and diseases of the musculoskeletal system.

Disease area	Number	Percentage
Mental and behavioural disorders	6	30%
Endocrine, nutritional, and metabolic diseases	4	20%
Diseases of the musculoskeletal system	3	15%

Disease area	Number	Percentage
Malignant neoplasms	2	10%
Diseases of the circulatory system	1	5%
Diseases of the digestive system	1	5%
Diseases of the ear	1	5%
Diseases of the urinary system	1	5%
Other	1	5%
Total	**20**	**100%**

Reference

Web-link to the scheme.

THE NETHERLANDS: INTRODUCTION

The Netherlands has two active innovative payment schemes:

- Small-Scale Experiments for the Introduction of Innovations, the focus of which is diverse and includes hospital medical procedures, in-vitro diagnostics, digital health technologies for use in home settings, but also non-med tech interventions, such as rehabilitation, psychology, etc.;
- Subsidy Scheme for Promising Care typically focuses on hospital medical devices and procedures and rarely on in-vitro diagnostics, drugs, and medical aids for use in home-care settings.

THE NETHERLANDS: SMALL-SCALE EXPERIMENTS

Title

Small-scale experiments for the introduction of innovations (Innovatie voor kleinschalige experimenten).

Objective

The objective of the pathway is to allow health care providers and insurance companies to have short-term, small-scale projects to improve the provision of care or make it more efficient. The scheme is considered as coverage with the evidence development program.

Overview

The program applies to procedures or programs that do not have enough evidence to obtain coverage within Basic Health Insurance. The program considers the innovative medical procedures that improve the organisation and provision of care to patients (also including online consultation, telemonitoring, home neuromodulation, school counselling, etc.). The care provider should be involved in the project.

The program covers the following topics:

- Introduction of new care delivery models with better cost-benefit ratio;
- Increasing efficiency of organisations;
- Improvement of quality of life of patients.

According to the policy rule "Innovation for small-scale experiments" (BR/REG-19158) of the Dutch Health Care Authority (NZa), the provider(s) and the insurer(es) develop an agreement and send it for approval to the NZa, which is the administrator of the program.

Experiments under the long-term care law (Wet langdurige zorg) are reimbursed with a maximum of €500,000 per project per year from an annual budget of €5 million. There is no defined project budget under the health insurance law (Zorgverzekeringswet).

The basic timeline of the project is three years, with the possibility of extending it up to five years. If the experiment is accomplished earlier, the Dutch Healthcare Authority (NZa) must be informed.

The NZa performs interim (mid of project timelines) and final evaluation of the experiment based on the evaluation report provided by the involved parties. The minimum requirements for the content of the interim and final evaluation report are provided in Article 7.1 of the policy rule.

The final evaluation should be provided to the NZa by the experimenting parties no later than six months before the end date of the experiment. Submitting the final evaluation, the experiment parties can request regular reimbursement (procedure code and/or tariff), an extension of the experiment,

or temporary maintenance of the consequences of the experiment (for phasing out an experiment or to obtain a regular reimbursement) from the NZa.

The NZa reports to the Minister of Health, Welfare and Sport on the results of the experiment. The experiment ends with the publication of a decree.

If an experiment has been extended, the experiment parties submit a new experiment evaluation to the NZa no later than six months before the end date of the extended experiment.

Care settings

In-patient, out-patient specialist settings, primary and community settings (home care and long-term care), nursing, and paramedical care.

Type of covered technologies

Medical procedures, digital health technologies, in-vitro diagnostics, and non-med tech interventions.

Inclusion criteria

The program covers the following topics:

- Introduction of new care delivery models with better cost-benefit ratio;
- Increasing efficiency of organisations;
- Improvement of quality of life of patients.

Applicant

A health care provider and an insurance company jointly develop and submit the application.

Stakeholders involved

Stakeholder	Role
Dutch Health Care Authority (NZa)	The administrator of the program

Role of the industry

Manufacturers of medical technologies cannot directly apply to the scheme.

Clinical and economic requirements for the scheme

There are no specific clinical or economic requirements for entering the program.

Statistics and trends about the use of the scheme

The document with ongoing experiments is frequently updated, and the data from the current version is provided (with the latest updates on August 11, 2022) (link).

As of August 11, 2022, there are 47 ongoing funded projects involving medical technologies and procedures:

- Outcome-oriented care for sexually transmitted infections (experimental introduction of a new STI care concept for sexually transmitted diseases based on integrated funding combined with eHealth, rapid decentralized diagnostics, and intelligent data management);
- Social approach to dementia (experimental integrated approach to ensure continuous appropriate support and care at early signs of dementia);
- Digital Combined Lifestyle Intervention program (a biennial fully digital program under the supervision of a professional lifestyle coach);
- Quit smoking (experiment dedicated to the care for heavily addicted smokers);
- Cognitive Neurorehabilitation (treatment of severe acquired brain injury with the cognitive neurorehabilitation program);
- Transmural palliative care with appropriate funding (experiment for the interdisciplinary transmural cooperation and deployment of care providers specialized in palliative care);
- Huntington (setting up an outpatient clinic for diagnostics, treatment, and outpatient care for Huntington's disease patients and gene carriers);
- CTG diagnostics for pregnant by a midwife in primary care (experiment to make CTG diagnostics possible for pregnant women in primary care, performed by a midwife);
- Centralized healthcare provision for obese children (the supervision and coordination of the integrated support and care for children with obesity);
- Point for Parkinson's (an experiment that focuses on the optimising of care provided for patients with Parkinson's disease);
- Lifestyle intervention for children (project to offer integrated, customized medical treatment in the field of nutrition, exercise, (lifestyle) behaviour, and underlying problems in children (up to 18 years) with an increased weight-related health risk);
- Acute care unit (unit intended as a 24/7 admission option for vulnerable elderly people with acute problems);
- District mental health care (improvement of care for psychologically vulnerable people by the mental health team, which focuses on a specific area – one metropolitan district or several village centres);
- Eye Movement Desensitization and Reprocessing (EMDR) therapy in virtual reality (use of virtual reality headset for EMDR therapy independently from the therapist);
- Pre-treatment "Stop-plan" for substance use (provision of interventions for patients who suffer from an alcohol and/or substance use disorder for prevention of abstinence and reduction of alcohol/substance use during the waiting period until the beginning of treatment)
- Night leave in mental health care units (experiment to allow recovering patients hospitalised for more than 30 days to go home for a night);
- Virtual reality cognitive behavioural therapy (project on cognitive behavioural therapy using Virtual Reality glasses);
- Complete home package (VPT) for forensic care (experiment for people with criminal or forensic care title, which will receive intensive individual guidance for independent life);

- Outpatient clinic for intensive chronic care (outpatient department for patients with several chronic conditions, in whom a monodisciplinary approach cannot provide the supervision required for effective treatment);
- Home-based rehabilitation after admission to geriatric department (the objective of the experiment is to significantly shorten the length of stay in geriatric settings and provide rehabilitation as much as possible at home using health apps);
- Hospital on Wheels (provision of medical care by nurse specialist at home or close to home for people with movement disorders due to physical or psychological reasons);
- REZUM for treatment of prostate enlargement (a minimally invasive treatment using steam for the treatment of lower urinary tract symptoms due to the enlarged prostate);
- Transmural cardiac rehabilitation (an exercise program performed by a primary care physiotherapist for cardiac rehabilitation);
- Multidisciplinary primary rehabilitation care (experiment related to people with chronic, non-specific pain of the musculoskeletal system and associated limitations);
- Community clinic: Acute care for the elderly in a short-term primary care facility (a new concept for the treatment of elderly people hospitalised due to acute diseases);
- Transition care unit (temporary home for families with a child with a complex chronic illness that requires constant supervision and specialized care);
- ReceptIVFity test (vaginal microbiome measurements with ReceptIVFity before starting an in vitro fertilization);
- KiECON (multidisciplinary diagnostics for children (0 to 7 years old) with complex multiple developmental problems);
- Airlift (digital solution for children with asthma);
- Bariatric surgery for adolescents (bariatric surgery by gastric bypass or gastric sleeve in adolescents with morbid obesity);
- Intensive rehabilitation in adolescents with severe brain injury (this initiative concerns a specialized clinic in which young people between the ages of 16 and 35 with severe (traumatic) brain injuries are intensively rehabilitated);
- Minimally invasive ablation of myomas (treatment of uterine fibroids by ultrasound-guided intrauterine ablation system Sonata);
- Prehabilitation for colon cancer surgery (intensive program in which the patient is actively stimulated to improve his physical condition, nutritional status, and mental resilience in a period of a few weeks before an operation);
- Advice Center for chronic pain (project for the optimisation of care for patients with chronic pain);
- Robotics for care support for people with psychiatric problems (use of robots in care for people with autism);
- Lifestyle guidance for children and young people with intensive care needs (preventive screening and advice of the multidisciplinary team (medical care, paramedical care, lifestyle, and the environment) for children and young people with intensive care needs);

- Professionalization of the medical and nursing service (strengthening of primary care by deploying nurse specialists and a nursing team);
- Full-fledged home through colourful unburdening (the experiment focuses on the guidance for a specific group of adult patients with an intellectual disability who require long-term care at home);
- Involvement of Coordinating Nurses in care for the disabled (deployment of nurses who are trained to identify health problems, perform proper triage, make nursing diagnoses and perform nursing interventions (Coordinating Nurses) in care provision for the disabled);
- Long-term intensive neurorehabilitation to prevent hopeless long-term disorders of consciousness (a proactive recovery-oriented treatment policy involving sketching and discussing the best and worst outcome scenarios and connection of the provided care to the scientific research);
- Promote support system (the client's support system at home, including motivational conversations);
- Nursing Home (an integral package of care and support at home to postpone or prevent admission to a nursing home);
- Social Robotics in Elderly care (project aimed at the use of robots as an aid in elderly care);
- Regional Department for patients with dementia and severe behavioural disorders;
- Chronic psychiatric nursing home care (project aimed at maintaining stability or improving the condition of patients with chronic psychiatric and somatic diseases);
- Quality nurse in care for the disabled (experiment aimed at supporting nurses specialized in care activities for people with intellectual disabilities);
- SOABB: Stabilization, Observation, Analysis, Treatment, and Guidance (experiment dedicated to elderly people with cognitive problems and aimed to improve the price/quality ratio of the necessary care).

From July 1, 2021, to August 11, 2022, 19 new projects have been funded. New projects are being included in the framework constantly throughout the year.

Number of selected projects for last nine years (2013 – August 11, 2022)

The total number of projects approved annually (not specifically related to medical technologies) is presented in the table below. A number of the project have been completed to date.

Status	2013	2014	2015	2016	2017	2018	2019-2020	2020-2021	2021-August 2022
Total number of approved projects	4	6	7	4	6	8	17	12	19

Reference

Web-link to the scheme.

THE NETHERLANDS: SUBSIDY SCHEME FOR PROMISING CARE

Title

Subsidy scheme for promising care (Subsidieregeling veelbelovende zorg).

Objective

The objective of the pathway is to support the development of missing evidence for promising care, which otherwise cannot be included for coverage in Basic Health Insurance. Evidence developed in the program should support a positive assessment by the Dutch Healthcare Institute (ZIN) in the future and inclusion in Basic Health Insurance. The scheme is considered coverage with the evidence development program.

Overview

Historically, coverage with evidence development was primarily available to procedures negatively assessed by the Dutch Healthcare Institute (ZIN) for inclusion into Basic Health Insurance but found promising. Only a limited number of technologies (about four-five per year) were entering the scheme. This limited the ability of the Dutch system to introduce innovative technologies.

In 2019, the old conditional reimbursement scheme (Voorwaardelijke toelating tot het basispakket) was replaced by the so-called "Subsidy scheme for promising care", focusing on establishing the effectiveness and cost-effectiveness of innovations. The program should make it possible to answer questions of the evaluation of conformity with science and practice to enable further inclusion into Basic Health Insurance. The study should include cost-effectiveness and national budget impact implications.

The Ministry of Health, Welfare and Sport allocates about €69 million annually for the scheme. Funds do not cover regular clinical care, already covered in the Basic Health Insurance, duplication of ongoing clinical research, extending current clinical research, and study with a duration of longer than six years.

Research funds can be spent on both the actual intervention (care provided to patients, defined in the "Inclusion criteria" chapter below) and research components (defined as all research directly related to the intervention). A maximum of 20% of the subsidy received can be spent on the research component. This means that 80% of the received subsidy must be used for the intervention part. If the research costs exceed 20% of the received subsidy, they can be funded from other, private resources.

The scheme is administered by the Dutch Healthcare Institute and the Dutch Organisation for Health Research and Development (ZonMw).

Application is made in two steps.

In the first step, an initial application is made by the healthcare provider with the project idea, which includes a description of the objective and relevance of the project, research proposal, endorsement by relevant parties, financial substantiation of cost, and reasoning why the project cannot be completed without a subsidy. Applications undergo evaluation for relevance and quality. A specific committee advises applicants about the further application process for the subsidy.

In the second step, the actual full application is submitted, which includes a description in English of the purpose and relevance of the project, a research proposal in English, a systematic literature review of the effectiveness and cost-effectiveness in English, a budget of the project, endorsement of the project by the relevant professional group or patient organisation, declaration of intent from each involved provider including several patients per provider, description of the termination procedure for the project and individual patients.

A specific committee advises the Executive Board of the Dutch Healthcare Institute on prioritizing the applications. The Board makes the final decision about which applications will receive the subsidy within five months of receiving the application. A project subsidy is granted for a maximum of six years (it could be extended to seven years). After the research project has ended, the Dutch Healthcare Institute (ZIN), within six months, will assess a decision on inclusion in Basic Health Insurance. The applicant is obliged to submit a final report to the Dutch Healthcare Institute no later than one month after the completion of the project.

It is possible to apply for the subsidy scheme twice a year. In 2022, the first round of the scheme for 2023 (round 7 in total) opened on February 1, 2022, with the deadline for the first wave of applications of September 29, 2022. The second round of application submission (round 8 in total) started on July 5, 2022, with a deadline of March 16, 2023, for applications.

Care settings

In-patient, out-patient specialist, and home-care settings.

Type of covered technologies

Medical devices, medical procedures, in-vitro diagnostics, pharmaceuticals, and medical aids.

Inclusion criteria

The program covers the following types of care:

- Medical procedures/care;
- Medical aids;
- Off-label use of pharmaceuticals registered in the Netherlands and use of non-registered advanced therapy medicinal products (ATMPs);
- Physiotherapy and remedial therapy;
- Administration of bacteriophages.

Only CE-marked medical devices are eligible for the program.

Applicant

Health care providers.

Stakeholders involved

Stakeholder	Role
Dutch Healthcare Institute (ZIN)	The administrator of the program. Makes decisions about funding on behalf of the Ministry
Dutch Organisation for Health Research and Development (ZonMw)	Co-administrator of the program

Role of the industry

Manufacturers of medical devices can participate in the application jointly with providers.

Clinical and economic requirements for the scheme

Submitted proposals should focus on technologies with a certain existing level of evidence. The program aims at producing missing clinical and economic evidence. However, the scheme accepts technologies without effectiveness demonstrated in randomised controlled trials.

The application includes a systematic literature review of clinical and cost-effectiveness evidence (published health economic studies) for the intervention.

Statistics and trends about the use of the scheme

In 2020, out of 38 submitted project ideas, five projects received a grant to carry out their research (a total of ca. €43 million) (link):

- Effectiveness of endolymphatic duct blockade (EDB) in patients with uncontrolled Ménière's disease;
- Use of new advanced FFRct technique in the diagnosis of patients with chest pain;
- Efficacy and cost-effectiveness of oral esketamine over electroshock therapy in patients with severe, non-psychotic, treatment-resistant depression;
- The effectiveness of Left Atrial Appendage Occlusion in patients with atrial fibrillation who cannot use anticoagulation;
- Research into the functioning of CAR-T cells produced "in-house".

In 2021, eight projects received a grant to carry out their research (a total of ca. €40 million) (link):

- Repetitive transcranial magnetic stimulation and in vivo exposure with response prevention in obsessive-compulsive disorder;

- MRI-guided laser-induced thermotherapy in glioblastoma;
- Personalized treatment with selective internal radiotherapy in elderly or vulnerable colon cancer patients with liver metastases;
- Structured, multidisciplinary, and person-centred intensive aftercare for patients at risk of health problems;
- Basophil Activation Test in children with possible IgE-mediated cow's milk allergy;
- Automatic regulation of blood glucose in type 1 diabetes (artificial pancreas);
- Knee dissipation compared to knee replacement in patients with severe knee osteoarthritis who do not respond adequately to conservative treatments;
- Use of trastuzumab and pertuzumab in HER2-positive oesophagal cancer.

In 2022, five projects (three projects – in March 2022, two projects – in April 2022) received a grant to carry out their research (a total of ca. €17.5 million) in the first round for 2022 (round 5 of the scheme) (link):

- Research of a new minimally invasive endoscopy-guided surgery in patients with spontaneous cerebral haemorrhage;
- Research into oral immunotherapy in children to cure a food allergy;
- Research on cutting the diaphragm band in chronic abdominal complaints;
- Transcatheter tricuspid valve repair in patients with severe leakage of the tricuspid valve in the heart;
- Precision radiation in patients with epilepsy.

In the second round for 2022 (round 6 of the scheme), out of 20 project ideas, four grant applications were submitted in March 2022. The decision on the awarded projects were expected to be published early October 2022.

Reference

Web-link to the scheme.

SPAIN: INTRODUCTION

Spain has two active innovative payment schemes in connection with the development of the Common Package of Benefits of the National Health System: the Monitoring Studies of methods, technologies, and procedures framework (actively used at the moment) and the Supervised Use of methods, technologies, and procedures framework (no new entrants since 2010). The scope of the programs includes any types of medical technologies suitable for inclusion in the Common Package of Benefits of the NHS (including technologies used in hospital settings, out-patient specialist settings, and home-care settings).

SPAIN: MONITORING STUDIES

Title

Monitoring studies of methods, technologies, and procedures (Estudios de monitorización de técnicas, tecnologías y procedimientos).

Objective

The objective of the scheme is to inform policy decision-making on public funding of relevant health technologies after their inclusion in the Common Package of Benefits of the National Health System (NHS). This scheme can be classified as coverage with evidence development program.

Overview

Monitoring studies are planned as observational studies to assess methods, technologies, and procedures (MTPs) after their introduction to the Common Package of Benefits of the NHS; if there is some uncertainty about their effectiveness in routine clinical practice, effectiveness in specific population groups, or if a high economic or organisational impact on NHS is expected.

Monitoring studies allow obtaining the necessary information to support future decisions on updating the Common Package of Benefits of the NHS. The Spanish Network of Agencies for the Evaluation of Health Technologies and Benefits (RedETS) plays an important role throughout this process.

The regulatory framework for carrying out monitoring studies of MTP was set in 2015 by Order SSI/1356/2015, of July 2.

The Commission of Benefits, Insurance, and Financing formulates the proposal to carry out the monitoring study at the initiative of other stakeholders (the Ministry of Health, Consumption and Social Welfare, the health administrations of the Autonomous Communities, the Mutualism for civil servants, or interested third parties).

In its decision, the Commission considers the suitability of the study to respond to the existing uncertainties about the MTP and its feasibility; this authority can also prioritise the monitoring studies to be carried out. The Ministry of Health, Consumption and Social Welfare decides on the submission of MTP to a monitoring study by resolution of the person in charge of the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System. The resolution establishes the specific technical requirements for each monitoring study and determines the Evaluation agency (normally – a regional HTA unit) that will be responsible for the technical coordination of the study.

The monitoring study is carried out in accordance with a protocol for a period of time proposed by the relevant Evaluation agency in the light of the characteristics of the MTP, the information to be obtained, and the periodicity of the follow-ups envisaged. All of this is ratified by the Commission of Benefits, Insurance, and Financing before the start of the information collection.

The first part of the protocol is developed by the Evaluation agency responsible for the technical coordination of the study and includes the following:

- Description of the MTP;
- Objective and justification of the study;
- Indications submitted to study;
- Initial conditions for the use of MTP: material, human, training requirements for its correct use, requirements that must be met by the hospitals where it is used, and quality controls.

The second part of the protocol is prepared by the Evaluation agency with the participation of other stakeholders (experts from the scientific societies, from the Ministry of Health, Consumption and Social Welfare, and the hospitals proposed by the Autonomous Communities). The conditions for the use of MTP included in the first part of the protocol can be ratified or modified, and the design of the study is established, specifying the methodology and the necessary sample size. The second part of the protocol contains the following sections:

- Inclusion and exclusion criteria for patients, specifying the indications included in the Common Package of Benefits of the NHS;
- Variables that allow obtaining relevant information for decision-making regarding patients and the MTP itself, referring to their results, adverse effects, and complications in the short, medium, and long term
- Variables that define subgroups of patients of special interest;
- Variables referring to the use of resources;
- Information on required follow-ups of the patients and their periodicity;
- Procedure for sending and receiving data and for monitoring compliance with the study protocol;
- Definition of alarms that allow the detection of relevant health problems that may arise during the study, and the mechanism of communication of such problems to the Ministry of Health, Consumption and Social Welfare, the Commission of Benefits, Insurance and Financing, and other competent health authorities (where appropriate).

The protocol is submitted to the Commission of Benefits, Insurance, and Financing for ratification.

All patients who meet the inclusion criteria set out in the protocol shall have the right to access the MTPs subject to a monitoring study in the hospitals proposed for the conduct of that study.

At the end of the monitoring study period, the relevant Evaluation agency draws up a technical report, which includes at least the following:

- Description of the MTP;
- Regulatory requirements for its application in Spain;
- The prior state of knowledge about its safety, efficacy, and degree of implementation in Spain;
- Results obtained from the monitoring study;

- Conclusions regarding:
    - Its efficacy, effectiveness, and efficiency and, where appropriate, its safety;
    - Its usefulness with respect to other existing alternatives;
    - The organisational implications of its introduction;
    - Its economic impact, including the estimation of the costs of its use in the NHS;
    - Recommendations on the most suitable conditions for the use of the MTP (if applicable).

The technical report is analysed by the Commission of Benefits, Insurance, and Financing; this will allow the initiation of the procedure of updating the Common Package of Benefits of the NHS (where appropriate).

Compensation for the care associated with monitoring studies for patients receiving it in an Autonomous Community other than that of their residence is provided through the Health Cohesion Fund (it means that funds are provided from the national source and not from individual Autonomous Communities).

The duration of accomplished monitoring studies was three to five years. To date, several monitoring studies have been ongoing for seven years.

Care settings

In-patient, out-patient specialist settings, and community settings (home care). Previous decisions in the scheme mostly concerned hospital technologies, with the exception of flash glucose monitoring technology.

Type of covered technologies

Medical devices, methods, and procedures that can be eligible for inclusion in the Common Package of Benefits, for which uncertainty about their effectiveness in routine clinical practice or effectiveness in specific population groups exists or if a high economic or organisational impact on NHS is expected. This typically relates to hospital devices and procedures.

The only example of the inclusion of medical aid in the community settings in the scheme is the flash glucose monitoring technology (2019).

Inclusion criteria

The framework is applicable to medical devices, methods, and medical procedures included in the Common Package of Benefits, for which uncertainty about their effectiveness in routine clinical practice or effectiveness in specific population groups exists, or if a high economic or organisational impact on NHS is expected.

General criteria for considering the MTPs relevant for evaluation:

- MTPs represent a substantially novel contribution to prevention, diagnosis, treatment, rehabilitation, improvement of life expectancy, or elimination of pain and suffering;
- There are new indications for existing equipment or products;
- MTPs require new specific equipment for their application;
- MTPs significantly modify the forms or organisational systems of patient care;
- MTPs affect broad sectors of the population or risk groups;
- MTPs assume a significant economic impact on the NHS;
- MTPs pose a risk to users or health professionals, or the environment.

Applicant

The Commission of Benefits, Insurance, and Financing formulates the proposal to carry out the monitoring study at the initiative of other stakeholders involved (listed in the table below).

Stakeholders involved

Stakeholder	Role
Ministry of Health, Consumption and Social Welfare	May propose the request to carry out the monitoring study In view of the proposal formulated by the Commission of Benefits, Insurance, and Financing, decides on the submission of MTP to a monitoring study by resolution of the person in charge of the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System. The resolution establishes the specific technical requirements for each monitoring study proposed by the Commission of Benefits, Insurance, and Financing and determines the Evaluation agency that will be responsible for the technical coordination of the study (with the favourable report of the corresponding Autonomous Community) General Directorate of the Common Package of Benefits of the National Health and Pharmacy System makes agreements with the manufacturers to evaluate the economic conditions of the product during the study period within the framework of shared risk management The General Directorate of the Common Package of Benefits of the National Health and Pharmacy System, together with the participation of Autonomous Communities, negotiates the supply and maximum price conditions of the devices under assessment with the industry representatives, requesting them to provide a quarterly communication of the number of devices/equipment supplied to each participating hospital. This periodic information is sequentially used to check the progression of included cases in each participating hospital in the electronic information system Experts from the relevant departments may participate in the development of the 2nd part of the protocol for the monitoring study

Stakeholder	Role
Commission of Benefits, Insurance, and Financing	Assesses the request to carry out the monitoring study considering the suitability of the study to respond to the existing uncertainties about the MTP and its feasibility, and formulates the proposal to carry it out May prioritise the monitoring studies to be carried out if considered necessary in the light of the applications received, considering the degree of uncertainty, health need, clinical utility, target population, and cost Ratifies the protocol of the monitoring study Analyzes the technical report prepared by the Evaluation agency
Autonomous Communities	May propose the request to carry out the monitoring study Propose hospitals where monitoring studies are to be carried out to the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System Facilitate the transfer of patients who require the use of any of the monitored MTPs in a similar way as the rest of the services from the Common Package of Benefits of the NHS and guarantee the accessibility of patients with disabilities Verify that the hospitals in their area provisionally proposed for carrying out the monitoring study have the conditions for the use of the method, technology, or procedure established in said protocol Submit the final proposal for participation in the study to the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System May participate in the process of making agreements between the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System and manufacturers regarding the evaluation of the economic conditions of the product during the study period, supply and maximum price conditions of the devices under assessment
Mutualism for civil servants	May propose the request to carry out the monitoring study May determine, with the favourable report of the respective Autonomous Community, the hospitals in which the MTP will be carried out in their field of management
Evaluation agency or Unit of the RedETS*	Is responsible for technical coordination of the monitoring study Draws up the protocol for the monitoring study Receives and processes information from the participating hospitals Prepares the technical report for submission to the Commission of Benefits, Insurance, and Financing

Stakeholder	Role
	If the study lasts more than one year, it also draws up annually a report which sets out the progress of the study for the Commission of Benefits, Insurance, and Financing Immediately communicates to the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System the serious adverse effects detected in the application of the method subject to monitoring study
Participating hospitals	May participate in the development of the 2nd part of the protocol for the monitoring study Follow the corresponding protocol and send to the Evaluation agency the data referred to in the protocol relating to their patients, respecting the established forms and deadlines May participate in the process of making agreements between the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System and manufacturers regarding the evaluation of the economic conditions of the product during the study period
Manufacturers	May provide additional / requested information about the product to the corresponding Evaluation Agency and General Directorate of the Common Package of Benefits of the National Health and Pharmacy System Agree with the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System regarding the evaluation of the economic conditions of the product during the study period within the framework of shared risk management Negotiates the supply and maximum price conditions of the devices under assessment with the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System with the participation of Autonomous Communities Provides a quarterly communication of the number of devices/equipment supplied to each participating hospital. This periodic information is sequentially used to check the progression of included cases in each participating hospital in the electronic information system

Note. *The HTA agencies that form part of the Spanish Network of Agencies for the Evaluation of Health Technologies and Benefits (RedETS) can be considered for this role: Basque Office for Health Technology Assessment (OSTEBA), Andalusian Health Technology Assessment Department (AETSA), Galician Agency for Health Technology Assessment (AVALIA-T), Agency for Health Quality and Assessment of Catalonia (AQuAS), Health Sciences Institute in Aragon (IACS), Agency for Training, Research and Health Studies of the Community of Madrid Pedro Laín Entralgo (UETS-MADRID), Health Institute Carlos III (ISCIII), Evaluation and Planning Service of the Canary Islands Health Service (SESCS)

Role of the industry

In monitoring studies involving the use of a medical device, the industry may have the following roles:

- Industry representatives have early access to both the preliminary monitoring study protocol and the preliminary final report to provide documented feedback. Manufacturers may provide the corresponding Evaluation agency with additional information that can contribute to both the development of the protocol and the technical report. This is done through the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System;
- Manufacturers shall provide the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System with the information requested about the product that contributes to solving the existing uncertainties that have generated the need to carry out a monitoring study, provided that it is not confidential information;
- The General Directorate of the Common Package of Benefits of the National Health and Pharmacy System, with the participation of the Autonomous Communities with hospitals involved in the study, makes agreements with the manufacturers to evaluate the economic conditions of the product during the study period within the framework of shared risk management. The General Directorate of the Common Package of Benefits of the National Health and Pharmacy System, together with the participation of Autonomous Communities, negotiates the supply and maximum price conditions of the devices under assessment with the industry representatives, requesting them to provide a quarterly communication of the number of devices/equipment supplied to each participating hospital. This periodic information is sequentially used to check the progression of included cases in each participating hospital in the electronic information system.

Clinical and economic requirements for the scheme

There are no clear requirements for the scheme. Technology should have established evidence sufficient to justify inclusion in the Common Package of Benefits, but with some uncertainties about their effectiveness in real-world settings (or specific populations) or anticipated high economic or organisational impact on NHS. Real-world evidence is not a prior requirement but an end result of the program.

Statistics and trends about the use of the scheme

Since the inception of the scheme until July 1, 2022, six MTPs had been included in the scheme (table).

As of July 1, 2022, two of the monitoring studies of MTPs were completed (link), and four are ongoing (link 1, link 2). The last MTP was approved for inclusion in the scheme in 2020.

Procedure	Evaluation agency	Approval dates	Execution period	Publication of final report	Required sample size	No. of referral centres
Biodegradable oesophagal stent for benign pathology	ICSIII	September 2015	April 2017 – October 2021	Not published yet	83	17

Procedure	Evaluation agency	Approval dates	Execution period	Publication of final report	Required sample size	No. of referral centres
Endobronchial valve for patients with persistent air leakage	SESCS	September 2015	June 2017 – 2020	2021	40	9
Percutaneous mitral valve repair system by clip*	OSTEBA	September 2015	April 2017 – October 2020	Not published yet	140	24
Closure device (Occluder) of the left atrial appendage**	ICSIII	September 2015	July 2017 – July 2021	Not published yet	150	27
Atrial assist device (LVAD) in the indication of permanent destination therapy	ACIS-Avalia-T	October 2020	2020	Not published yet	30	Ongoing designation of referral centres
Glucose Monitoring System using sensors (Flash type) for type 1 diabetes mellitus in childhood and adolescence	SESCS	August 2018	April 2019 – March 2021	2021	343	27

Note. Approval dates, execution period, required sample size, and no. of referral centres are provided according to: Serrano-Aguilar P et al. (2021). Postlaunch evidence-generation studies for medical devices in Spain: the RedETS approach to integrate real-world evidence into decision making. International Journal of Technology Assessment in Health Care 37, e63, 1–8. https://doi.org/10.1017/S0266462321000295

Note. *For patients with severe symptomatic mitral regurgitation (≥ 3+) refractory to optimal medical treatment, with a life expectancy of at least one year, in which a multidisciplinary team has determined an excessive risk to be operated on by open surgery and comorbidity that does not threaten the expected benefit of reducing mitral regurgitation, and meet appropriate anatomical criteria (the primary jet is caused by poor coaptation of the middle segments -A2 and P2- of the mitral leaflets)

Note. **For patients with atrial fibrillation, with the presence of other risk factors for stroke added and contraindication or intolerance to oral anticoagulation therapy or for patients who are going to undergo a percutaneous intervention of the mitral valve and have atrial fibrillation, high risk of stroke and contraindication or intolerance to oral anticoagulation therapy

This is an example of decision-making on the basis of the results of the monitoring study:

- The monitoring study regarding endobronchial valves for patients with persistent air leakage was completed in June 2020;

- The technical report prepared by the Evaluation and Planning Service of the Canary Islands Health Service (SESCS) was analysed by the Commission of Benefits, Insurance, and Financing in January 2021;
- In June 2021, the agreement made by the Commission of Benefits, Insurance, and Financing was discussed at the plenary session of the Interterritorial Council for the National Health System;
- In July 2021, the Resolution of the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System was published, outlining that the endobronchial valves for persistent air leakage should be kept in the Common Package of Benefits of the National Health System under the same conditions as in the monitoring study protocol.

Reference

Web-link to the scheme.

SPAIN: SUPERVISED USE OF TECHNOLOGIES

Title

Supervised use of methods, technologies, and medical procedures (Uso tutelado de técnicas, tecnologías y procedimientos sanitarios).

Objective

The objective of the scheme is to inform decision-makers about the value of health methods, technologies, and medical procedures before their inclusion in the Common Package of Benefits of the National Health System (NHS). This scheme can be classified as coverage with evidence development program.

Overview

Supervised use can be considered as a mechanism to determine the degree of safety, efficacy, effectiveness, or efficiency of a method, technology, or procedure (MTP), in cases where there is not enough information to support its inclusion in/exclusion from the Common Package of Benefits of the NHS.

The results obtained during the supervised use may be used for the inclusion, modification of conditions of use, or exclusion of methods, technologies, and procedures in the Common Package of Benefits of the NHS.

The regulatory framework for the scheme was introduced in 1995 via the Royal Decree 63/1995; however, the first pilot project was implemented in 1999. The Law 16/2003 of May 28 once again emphasised the need for evaluation to update the content of the Common Package of Benefits of the NHS. This Law has given supervised use the legal and financial foundation it needed.

The Commission of Benefits, Insurance, and Financing formulates the proposal to carry out the supervised use at the initiative of other stakeholders (Ministry of Health, Consumption and Social Welfare, Autonomous Communities, HTA agencies, and participating hospitals). After the agreement by the Interterritorial Council for the National Health System (CISNS), the Ministry of Health, Consumption and Social Welfare authorises the supervised use. The Autonomous Communities propose the hospitals where the supervised use will be carried out to the Ministry of Health, Consumption and Social Welfare for authorisation. Supervised use is carried out at these authorised hospitals.

After having confirmed the inclusion of the MTP in the supervised use program, the Supervisory evaluation body draws up the protocol with the participation of experts and the hospitals where the supervised use will be carried out. The protocol aims at guaranteeing safety, respect for bioethics, and the achievement of results relevant to knowledge. The protocol covers the following:

- The objective of the supervised use;

- Indications, including the inclusion and exclusion criteria for patients;
- Conditions of use of the MTP;
- The mechanism for the detection of problems relevant to health that may arise during the realisation of the supervised use and communication of these problems to the Ministry of Health, Consumption and Social Welfare (then this data might be transferred to the Commission of Benefits, Insurance, and Financing and other competent health authorities);
- Relevant information to be collected about patients, the MTP itself, the results and complications in the short, medium, and long term, which supports decision making;
- Procedure for collecting information and monitoring compliance with the study protocol;
- Estimation of the duration of the supervised use, depending on the need to obtain information;
- Estimation of the costs of its implementation in the NHS.

All patients who meet the selection criteria established in the corresponding protocol will have the right to access the MTPs in supervised use on equal terms with patients residing in Autonomous Communities where the authorised hospitals for the realisation of supervised use are located.

After the supervised use of the MTP, the Supervisory evaluation body prepares the technical report, which aims to provide objective information to decide on the financing of the method in the NHS. The report includes at least the following data:

- Description of the operational MTP;
- State of knowledge about its safety, efficacy, cost, and degree of implementation in Spain;
- Regulatory requirements for the application of the MTP in Spain;
- Results obtained from the supervised use;
- Conclusions on the safety, efficacy, and efficiency of the MTP; its usefulness with respect to existing MTPs; the organisational impact of its introduction; its economic impact; recommendations on the most suitable conditions for applying the MTP (where appropriate).

The supervised use is financed by the national Health Cohesion Fund for all patients that are cared for in the hospitals specifically authorised for this (it means that financing comes from a central source and not from individual Autonomous Communities). Funding is provided during the period of supervised use for the cases included in the annual report by the Supervisory evaluation body according to the amounts provided in Annex IV of Royal Decree 207/2010, of February 26, 2010.

The duration of supervised use of a method is three to six years. There is no information available regarding this program being discontinued in the future, despite not MTPs being included in the scheme since 2010.

Care settings

In-patient, out-patient specialist settings, and community settings (home care). Previous decisions in the scheme mostly concerned hospital technologies, with the exception of positron emission tomography (PET).

Type of covered technologies

Medical devices, methods, and procedures that can be eligible for inclusion in the Common Package of Benefits. Typically, hospital procedures were included. The only out-patient specialist procedure included was positron emission tomography (PET).

Inclusion criteria

Supervised use is proposed as a mechanism for updating the Common Package of Benefits. It is applicable to certain MTPs on which there is not enough evidence to be able to prepare an evaluation report or to make a statement on the safety, efficacy, and efficiency by the authorities.

The general criteria for considering the MTPs relevant to the scheme are:

- MTPs represent a substantially novel contribution to prevention, diagnosis, treatment, rehabilitation, improvement of life expectancy, or elimination of pain and suffering;
- There are new indications for existing equipment or products;
- MTPs require new specific equipment for their application;
- MTPs significantly modify the forms or organisational systems of patient care;
- MTPs affect broad sectors of the population or risk groups;
- MTPs assume a significant economic impact on the NHS;
- MTPs pose a risk to users or health professionals, or the environment.

Applicant

The Commission of Benefits, Insurance, and Financing formulates the proposal to carry out the supervised use at the initiative of other stakeholders involved (listed in the table below).

Stakeholders involved

Stakeholder	Role
Ministry of Health, Consumption and Social Welfare	Authorises the supervised use of MTPs at its own initiative or at the proposal of the corresponding public health administration bodies, with the prior agreement of the Interterritorial Council for the National Health System (CISNS)
Interterritorial Council for the National Health System (CISNS)	Debates and issues recommendations and agreements on the supervised use of certain MTPs
Commission of Benefits, Insurance, and Financing	Formulates the proposal to carry out the supervised use at the initiative of the Ministry of Health, Consumption and Social Welfare or any of the Autonomous Communities, including the Supervisory evaluation body (selected from those participating in the update of the Common Package of Benefits of the NHS), and the hospitals in which it will be carried out

Stakeholder	Role
	Analyzes the technical report Proposes to update the Common Package of Benefits of the NHS (based on the results of the supervised use)
Autonomous Communities	May propose the MTP for introduction in the supervised use Propose the hospitals where the supervised use will be carried out. Guarantees that these hospitals have appropriate safety and quality conditions, sufficient experience, knowledge, and human and material resources necessary for the realisation of the MTP and that the hospitals will follow the agreed protocols
Supervisory evaluation bodies*	May propose the MTP for introduction in the supervised use Determines the material, personal, and training requirements for the proper use of the MTP Develops a protocol for the selection and monitoring of patients and the assessment of the results Verifies that the medical devices or other products necessary for the application of the MTP, or the facilities where it is carried out, satisfy the requirements of the specific regulations Collects and processes information from the participating hospitals Prepares the technical report If the duration of the supervised use is more than one year, prepare an annual report in which the evolution data of the supervised use is collected Immediately communicates to the Ministry of Health, Consumption and Social Welfare the serious adverse effects detected in the application of the MTP subject to supervised use
Participating hospitals	May the MTP for introduction in the supervised use Forward to the Supervisory evaluation body, the information referred to in the protocol relating to their patients, respecting the established forms and deadlines

Note. *The HTA agencies that form part of the Spanish Network of Agencies for the Evaluation of Health Technologies and Benefits (RedETS) can be considered for this role: Basque Office for Health Technology Assessment (OSTEBA), Andalusian Health Technology Assessment Department (AETSA), Galician Agency for Health Technology Assessment (AVALIA-T), Agency for Health Quality and Assessment of Catalonia (AQuAS), Health Sciences Institute in Aragon (IACS), Agency for Training, Research and Health Studies of the Community of Madrid Pedro Laín Entralgo (UETS-MADRID), Health Institute Carlos III (ISCIII), Evaluation and Planning Service of the Canary Islands Health Service (SESCS)

Role of the industry

There is no specific role for the industry regarding this particular scheme.

However, the industry can initiate a request for the inclusion of the novel technology or procedure in the Common Package of Benefits or provide additional information to relevant stakeholders on request.

Clinical and economic requirements for the scheme

There are no clear requirements for the scheme. Technology should have established evidence, but the evidence must have some gaps that prevent it from inclusion in the Common Package of Benefits.

Statistics and trends about the use of the scheme

Since the inception of the scheme until July 1, 2022, seven MTPs have been included in the scheme (link 1, link 2) (table).

The last MTP was included in the scheme in 2010, and this MTP was supervised until 2015. No MTPs have been used under supervision (under this framework) since 2010.

There is no information on this scheme being discontinued, despite no MTPs being included since 2010.

Title	Supervisory evaluation body	Evaluation period
Effectiveness of non-pharmacological treatments for Parkinson's	AETSA	2001 - 2005
Appropriate use of positron emission tomography (PET) in selected and protocolized clinical situations	ISCIII	2001 – 2005
Appropriate use of endoprosthesis in abdominal aortic aneurysm	ISCIII	2001 - 2004
Appropriate use of epilepsy surgery	OSTEBA	2000 - 2004
Efficacy of chondrocyte transplantation	AVALIA-T	2000 - 2006
Appropriate use of the artificial anal sphincter	ISCIII	2000 - 2003
Surgical treatment of facial lipoatrophy associated with HIV-AIDS	Not available	2010 - 2014

In October 1999, the CISNS proposed six MTPs for supervised use as a pilot project. These MTPs are the first six mentioned in the table above. The information obtained through supervised use for these MTPs was presented to the Commission of Benefits, Insurance, and Financing and served as the basis for decision-making on the inclusion of considered MTPs in the Common Package of Benefits (e.g., the inclusion of PET in oncological indications).

The supervised use of the surgical treatment of facial lipoatrophy associated with HIV-AIDS was launched after the publication of Royal Decree 207/2010 of February 26, which established the conditions for the supervised use of health methods, technologies, and procedures. This Decree also

modified Royal Decree 1207/2006 of October 20, which regulates the management of the Health Cohesion Fund. Based on the data obtained from the supervised use of surgical treatment of facial lipoatrophy associated with HIV-AIDS, the Common Package of Benefits of the NHS was modified with the inclusion of this method specifically for the treatment of HIV (Order SSI/1356/2015 of July 2).

The Royal Decree 207/2010, of February 26, 2010, specifies that MTPs subject to supervised use are set out in Annex IV of this Royal Decree. It is outlined that this Annex shall be reviewed periodically by Ministerial Orders to include MTPs for which supervised use will be in force at any given time in the future. However, as of July 1, 2022, this Royal Decree, including its Annex IV, was never updated.

Reference

Web-link to the scheme.

SWITZERLAND: INTRODUCTION

Switzerland has one active innovative payment scheme: the so-called provisional reimbursement of medical procedures, which is focused on medical procedures delivered by physicians and chiropractitians, typically performed in hospital settings (and rarely in out-patient specialist settings). Also, medical aids and IVD tests can receive temporary reimbursement while generating missing evidence required for a decision about regular reimbursement.

SWITZERLAND: PROVISIONAL REIMBURSEMENT OF PROCEDURES

Title

Provisional reimbursement of medical procedures (in German: Leistungen in Evaluation; in French: les Prestations en Cours d'Évaluation; in Italian: le Prestazioni in Valutazione).

Objective

The objective of the scheme is to provide temporary reimbursement for medical procedures where existing evidence is insufficient to decide whether or not coverage unlimited in time is warranted. The scheme applies to novel, promising, and already covered (contested for efficacy or obsolescence) medical procedures. During this defined period, further evidence is collected. The scheme is classified as coverage with evidence development program.

NB! Medical aids and IVD tests can also receive Coverage with Evidence Development if there is a need to generate more evidence in order to make a final reimbursement decision. These are connected to different reimbursement processes (inclusion of new tests in the List of Analyses, and inclusion of new medical aids in the List of Tools and Appliances). Due to similarities of the process of coverage with evidence development, the other two schemes were not elaborated on, except for the statistical data. The concept of coverage with evidence development is presented using the example of medical procedures (Annex 1 of KLV/OPre List).

Overview

The provisional reimbursement of medical procedures (Leistungen in Evaluation), coverage with evidence development (CED) scheme, was introduced in Switzerland in 1996.

According to the principle of trust, medical procedures provided in hospital settings are covered by the Swiss statutory health insurance (SHI) scheme without formal health technology assessments (HTA). However, in cases where there is doubt regarding efficacy, appropriateness, and cost-effectiveness, the evaluation of medical service can be requested by anyone with a legitimate interest. Typically, the insurance companies challenge the coverage of already reimbursed procedures, but other stakeholders, including the manufacturer, hospitals, clinical societies, patient organisations, or even the Federal Office for Public Health (FOPH), can request the evaluation of a medical (new or already covered) service.

The requests for evaluation of medical procedures are submitted to the Federal Commission for Medical Benefits and Basic Principles (ELGK/CFPP) of the FOPH, which requests the applicant to submit all available evidence on the effectiveness, appropriateness, and cost-effectiveness of the method. The Medical Benefit Section (MBS) of the FOPH checks the completeness of the evidence submitted, performs the assessment (based on the evidence submitted), and prepares a report which

includes a summary and indication of critical issues. The MBS forwards the assessment report for an appraisal by the ELGK/CFPP. Based on the recommendation by the ELGK/CFPP, the final decision is taken by the Federal Department of Home Affairs (EDI/FDI) in the form of one of three possible outcomes:

- Yes – continued coverage (with or without limitations such as indications, second-line use, by certain providers only, etc.);
- No – exclusion from coverage;
- Yes, in evaluation – coverage while further evidence is collected.

Before 2014, a fourth possible outcome was "No, in evaluation." The status "Yes, in evaluation," which means CED with reimbursement, can be connected to certain conditions, for example, an establishment of a patient-based register or limiting reimbursement to specific indications, centres, or medical specialists. The status is set for a specific period, which can be extended until evidence is complete.

Decisions are documented in Annex 1 of the health care benefit ordinance (KLV/OPre).

The evaluation period differs for each individual technology but typically lasts two to five years. The evaluation period can be prolonged and sometimes lasts more than a decade. For example, the original evaluation period for extracorporeal photopheresis in obliterating bronchitis syndrome was 2009-2016, but the evaluation period was prolonged first to 2020, then to 2022, and then to the end of 2024 (a total of 15 years under evaluation). The changes are reflected in the updated versions of the KLV/OPre Annex I, which is typically updated twice a year with effective dates from January 01 and July 01.

Furthermore, medical aids and IVD tests can also receive Coverage with Evidence Development if there is a need to generate more evidence in order to make a final reimbursement decision. However, the decision to grant temporary coverage to medical aids and IVD tests is a consequence of a mandatory evaluation process, the goal of which is the inclusion of medical aids / IVD tests in their respective positive reimbursement Lists (i.e., the List of Tools and Appliances, and the List of Analyses). Those processes are not related to the process described in this chapter but are similar to this one.

Decisions are documented in Annexes 2 (List of Tools and Appliances) and 3 (List of Analyses) of the health care benefit ordinance (KLV/OPre).

Care settings

Regarding Annex 1 (procedures), the in-patient setting is the most relevant. However, there are some examples of where out-patient settings were relevant (e.g., multigene expression test in breast cancer. Examination of tumour tissue of a primary, invasive breast cancer. This also indicates that, in rare cases, complex genetic tests can be considered under the main Coverage with Evidence Development framework).

Regarding Annex 2 (medical aids), the home-care setting is relevant.

Regarding Annex 3 (IVD tests), the out-patient setting is relevant.

Type of covered technologies

Medical procedures, in-vitro diagnostic and genetic tests, and medical aids.

Inclusion criteria

No specific inclusion criteria exist. The scheme can be considered for an innovative technology when there is still uncertainty as to whether the technology provides an added value in relation to the other therapeutic options.

Applicant

The evaluation of medical procedures can be requested by anyone with a legitimate interest. Typically, the insurance companies challenge the coverage of already reimbursed procedures, but other stakeholders, including the manufacturer, hospitals, clinical societies, patient organisations, or even the Federal Office for Public Health (FOPH), can request the evaluation of a medical (new or already covered) service.

Provisional reimbursement cannot directly be applied for; rather, it is one of three possible outcomes of the evaluation for coverage in Switzerland.

Stakeholders involved

The following stakeholders are involved.

Stakeholder	Role
Applicant	Request for evaluation of eligibility for coverage within the statutory health insurance of a medical service The applicant is also responsible for submitting the evidence upon which the evaluation will be based The applicants may be insurance companies, manufacturers, hospitals, clinical societies, patient organisations, or the Federal Office for Public Health (FOPH)
Medical Benefit Section (MBS)	Checks the completeness of evidence submitted, performs the assessment (based on the evidence submitted), and prepares an evaluation report
Federal Commission for Medical Benefits and Basic Principles (ELGK/CFPP)	Performs the appraisal of the evaluation report

Federal Department of Home Affairs (EDI/FDI)	Makes a final decision about coverage (yes; no; yes, in evaluation)

Role of the industry

The manufacturers of medical technologies may apply for the evaluation of medical procedures. Manufacturers typically apply for evaluation of novel procedures in order to obtain guaranteed coverage of those novel procedures (by having them evaluated and included in Annex 1 of the KLV/OPre list). If the manufacturers are the applicants, they must also submit the evidence upon which the assessment will be performed, as this is the responsibility of the applicant.

Clinical and economic requirements for the scheme

For a technology to be eligible for provisional reimbursement, all the following questions (besides question number 3) must be answered positively:

1. Is there a critical evidence gap? Most relevant in relation to effectiveness, safety, economic data, and conditions of use;
2. Is there interest in the technology/test from a national healthcare perspective? I.e., it regards a severe or high incidence disease, improves care and patient outcomes, or has a significant economic impact;
3. Is there national or international ongoing research that can fill the evidence gap? I.e., independent studies, post-marketing trials, or registries that are applicable to Switzerland and available within a reasonable timeframe;
4. Can a research question be defined? A research question should contain information on patient/population, intervention/test, comparator (if available), and clinical outcome;
5. Is CED feasible? In relation to timeframe, study design, finances, availability of a competent and willing investigator, market and/or ethical regulations, and alternative research;
6. Is the estimated balance between the value and costs of conducting CED favourable?
7. Will the new evidence justify a potential change in the coverage decision?

More details about the requirements are provided in checklists for medical interventions and diagnostic tests by the FOPH.

Statistics and trends about the use of the scheme

Medical procedures – Annex 1 of KLV/OPre

As of July 01, 2022, there are 21 medical procedures under this framework (link) (table).

Procedure name	Evaluation period
Lymphovenous anastomosis and vascularized lymph node transplantation for the treatment of lymphedema	1.7.2021 until 31.12.2026

Procedure name	Evaluation period
Liposuction to treat pain associated with lipedema	1.7.2021 until 31.12.2025
Metabolic surgery (patient with type 2 diabetes mellitus, which is difficult to control and body mass index (BMI) of 30 – 35)	1.1.2021 / 1.7.2021 until 31.12.2025
Autologous chondrocyte transplantation for the treatment of post-traumatic lesions of knee joint cartilage and cartilage lesions in osteochondritis dissecans in the knee joint	1.1.2002 / 1.1.2004 / 1.1.2017 / 1.1.2020 / 1/1/2021 until 31/12/2024
Autologous fat transplantation for postoperative reconstruction of the breast	1.7.2018 until 30.6.2023
Extracorporeal photopheresis in obliterating bronchitis syndrome following lung transplantation	1.1.2009 / 1.8.2016 / 1.1.2020 / 1.1.2022 until 31.12.2024
Endovascular therapy of vascular erectile dysfunction: endovascular revascularization of the arteries supplying the penis; endovascular embolization therapy of the veins draining the penis	1.1.2022 / 1.7.2022 until 31.12.2025
Transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis who have a medium surgical risk	1.7.2020 until 30.6.2023
Focused ultrasound therapy in the pallidum, thalamus, and subthalamus for the treatment of severe, chronic, therapy-resistant neuropathic pain	15.7.2015 / 1.7.2020 / 1.1.2021 until 31.12.2025
Multigene expression test in breast cancer. Examination of tumour tissue of a primary, invasive breast cancer	1.1.2011 / 1.1.2015 / 1.1.2019 until 31.12.2023
Hematopoietic stem cell transplantation - autologous - in cases of Ewing sarcoma, soft tissue sarcomas, Wilms tumour	1.1.2002 / 1.1.2008 / 1.1.2013 / 1.1.2018 until 31.12.2022
Hematopoietic stem cell transplantation - autologous - in cases of autoimmune diseases with the exception of systemic sclerosis, multiple sclerosis, Crohn's disease, and diabetes mellitus	1.1.2002 / 1.1.2008 / 1.1.2013 / 1.1.2018 until 31.12.2022
Hematopoietic stem cell transplantation - autologous - in multiple sclerosis	1.7.2018 until 30.6.2024
Hematopoietic stem cell transplantation - allogenic - in cases of autoimmune diseases	1.1.2002 / 1.1.2008 / 1.1.2013 / 1.1.2018 until 31.12.2022
CAR-T-cell therapy (CAR = chimeric antigen receptor) with Tisagenlecleucel: in the case of relapsed or treatment-refractory diffuse large B-cell lymphoma	1.1.2020 until 31.12.2022
CAR-T-cell therapy (CAR = chimeric antigen receptor) with Axicabtagen-Ciloleucel: in relapsed or refractory diffuse large-cell B-cell lymphoma	1.1.2020 until 31.12.2022
CAR-T-cell therapy (CAR = chimeric antigen receptor) with Brexucabtagene Autoleucel in adults with refractory or relapsed mantle cell lymphoma	1.7.2022 until 1.7.2027

Procedure name	Evaluation period
Embolization of the prostate arteries in symptomatic benign prostatic hyperplasia in patients with moderate to severe obstructive symptoms (IPSS >8, QoL >3) with prostatic hyperplasia > 30-50 ml	1.7.2022 until 31.12.2024
Proton therapy for non-small cell lung cancer (NSCLC) UICC stages IIB and IIIA / B, as part of the randomised controlled study RTOG 1308	1.4.2020 until 31.12.2025
Proton therapy in locally advanced esophageal carcinoma (≥ T2 or N+, M0), as part of the randomised controlled PROTECT study	1.1.2022 until 31.12.2026
Regional deep hyperthermia for tumour therapy in combination with external radiation therapy or brachytherapy for the following indications: - Soft tissue sarcoma (maintenance of function) if chemotherapy is contraindicated - Local tumour recurrences with compression symptoms in a palliative situation, focal depth > 5 cm	1.1.2017 / 1.1.2019 1.7.2021 until 30.6.2023

Six new medical procedures obtained coverage with evidence development in the period July 01, 2021 – July 01, 2022:

- Lymphovenous anastomosis and vascularized lymph node transplantation for the treatment of lymphedema;
- Liposuction to treat pain associated with lipedema;
- Endovascular therapy of vascular erectile dysfunction: endovascular revascularization of the arteries supplying the penis and endovascular embolization therapy of the veins draining the penis;
- Embolization of the prostate arteries in symptomatic benign prostatic hyperplasia;
- CAR-T-cell therapy (CAR = chimeric antigen receptor) with Brexucabtagene Autoleucel in refractory or relapsed mantle cell lymphoma;
- Proton therapy in locally advanced oesophagal carcinoma (≥ T2 or N+, M0), as part of the randomised controlled PROTECT study.

For the following medical procedures, in the period July 01, 2021 – July 01, 2022, the evaluation was prolonged:

- For "regional deep hyperthermia for tumour therapy in combination with external radiation therapy or brachytherapy in soft tissue sarcoma (maintenance of function) if chemotherapy is contraindicated and local tumour recurrences with compression symptoms in a palliative situation, focal depth > 5 cm", evaluation was prolonged on July 01, 2021, and will last until June 30, 2023;
- For "extracorporeal photopheresis in obliterating bronchitis syndrome following lung transplantation, when augmented immunosuppression and treatment with macrolides were unsuccessful," evaluation was prolonged on January 01, 2022, and will last until December 31, 2024.

The procedure "Focused ultrasound therapy in the pallidum, thalamus, and subthalamus for the treatment in confirmed diagnosis of idiopathic Parkinson's disease, progression of the disease symptoms over at least two years, inadequate symptom control dopamine treatment (off phenomenon, on/off fluctuations, on dyskinesia)" which was in evaluation in July 2021, received the status "Yes" (regular coverage) on January 01, 2022.

Among the 21 medical procedures currently provisionally reimbursed, the most common type of technology was cell therapy (n=7; 33.3%).

The table below shows the number of medical procedures covered by provisional reimbursement in the last three years.

v 01.01.2020	v 01.07.2020	v 01.01.2021	v 01.07.2021	v 01.01.2022	v 01.07.2022
16	16	16	18	19	21

Medical aids – Annex 2 of KLV/OPre

As of July 01, 2022 (List of Tools and Appliances, version of July 01, 2022), there were 17 categories of medical aids under evaluation (link).

Category of medical aids	In evaluation until
Elbow bandages (all six items in chapter 05.08)	31.12.2024
Vest with defibrillator including instruction, 24-hour emergency service, readiness, replacement of electrodes and other consumables (Wearable Cardioverter Defibrillator)	31.12.2022
TTFields for the treatment of recently diagnosed glioblastoma	30.06.2024
Compressed oxygen cylinders of all sizes	31.12.2026
Liquid oxygen from 20 to 25 L	31.12.2026
Liquid oxygen from 30 to 50 L	31.12.2026
First technical instructions and initial adjustment of a CPAP device by technicians from the delivery centre	31.12.2022
First technical instructions and initial adjustment of the servo ventilation devices and the bi-level PAP devices by the technicians of the delivery centre	31.12.2022
First technical instructions and the initial adjustment of mechanical ventilation devices at home by technicians from the delivery centre	31.12.2022
Pulse oximeter for outpatient surveillance of acute COVID-19 patients at home	30.06.2024
Outpatient surveillance of acute COVID-19 patients at home	30.06.2024

Category of medical aids	In evaluation until
Orthosis for immobilisation of the hip joint, adjustable position	31.12.2023

In-vitro diagnostics – Annex 3 of KLV/OPre

As of July 01, 2022 (List of Analyses, version of February 01, 2022), there were four tests under evaluation (link).

Test	In evaluation until
Screening of newborns for phenylketonuria, galactosemia, biotinidase deficiency, adrenogenital syndrome, congenital hypothyroidosis, medium chain acyl-CoA-dehydrogenase deficiency (MCAD), cystic fibrosis, maple syrup urine disease (MSUD), glutaric aciduria type 1 (GA-1) and severe congenital immunodeficiencies	31.12.2024
SARS-coronavirus-2 (SARS-CoV-2, genotype determination)	31.12.2023
SARS-coronavirus-2 (SARS-CoV-2), Ig or IgG	31.12.2023
Molecular genotyping of human leukocyte antigen (HLA), locus A, B, C, DRB1, DRB3 / 4/5, DQA1, DQB1, DPA1 and DPB1	30.06.2023

Reference

Web-link to the scheme (medical procedures).

Web-link to the scheme (medical aids).

Web-link to the scheme (IVD tests).

NEXT STEPS

Healthcare systems in Europe are not static. Over the last few years, a number of innovative payment schemes were abolished (mostly in the UK and one in the Netherlands), and several new schemes emerged (in Belgium, the UK, France, Germany, and the Netherlands). New schemes cover both traditional types of procedures and technologies (e.g., transitional coverage programs in France) and digital technologies (temporary reimbursement of software applications in Belgium, provisional listing of digital health applications in Germany).

Within a year period, it will be valuable to observe the experience with the recently established innovative payment schemes (real-world application of the scheme, number of new entrants, etc.):

- Belgium - Temporary Reimbursement of Software Applications (level 3-);
- France – transitional coverage of medical procedures (CCAM) and medical devices (pre-LPPR).

For two newly established schemes, operational characteristics will become available, and it will be possible to observe the first real-world experience with the schemes:

- France - Early Coverage framework for innovative digital medical devices;
- Scotland - Accelerated National Innovation Adoption (ANIA) Pathway.

It is recommended to establish a regular timeframe (e.g., every 1–1.5 years) for a routine update of the report, including new emerging schemes, requirements and criteria for already identified schemes, real-world experience, and the impact of the schemes.

Call to action

In Europe, reimbursement and funding of medical procedures and technologies are conceived and provided independently by each country. Every country has its specific system resulting from its own particular political, administrative, and constitutional structure and this has led to, amongst others, a significant disparity across European countries in the number and use of pathways that enable timely market access to innovative medical technologies (digital health technologies, medical devices, in vitro diagnostics) and medical procedures.

All European patients need early access to these promising technologies and procedures to improve their quality of life. These pathways also benefit the providers and healthcare professionals (by improving effectiveness, quality of care and clinical outcomes), the healthcare systems and payers (by optimising the use of healthcare resources and providing societal value). Finally, they encourage the industry to develop new technologies.

With this project, a mapping of all the pathways enabling market access to innovative medical procedures and technologies has been developed through the screening of the situation in 32 European countries between July and October 2022.

Its goal was to give an overview of 1) all the current payment schemes for innovative digital health technologies, medical devices, in vitro diagnostics and medical procedures and 2) the current concrete

political initiatives aimed at transforming healthcare systems and/or reimbursement and funding systems already implemented by some European countries.

As previously indicated, to date, only one fourth of the screened countries have introduced and administer innovative payment schemes covering digital health technologies, medical devices, in vitro diagnostics, or medical procedures. It is however essential to note that the existence of (a) scheme(s) in a country is not automatically a guarantee of improved and timely access to medical technologies as only those schemes which are adequately designed, implemented and managed will offer such access.

In terms of political initiatives aimed at transforming healthcare systems and/or reimbursement and funding systems, the screening has shown that even if several countries are indeed taking concrete initiatives in this direction, the overall political commitment to change the systems remains limited.

To enable improved and timely access to promising digital health technologies, medical devices, in vitro diagnostics and medical procedures, appropriate coverage schemes must be developed, implemented and administrated across all European countries. In addition, timely and ambitious political initiatives focused on improving healthcare systems' quality and delivery of care through optimal reimbursement and funding mechanisms must be put in place in these countries.

By completing the mapping of European countries having pathways enabling market access to innovative medical procedures and technologies, the first step in this direction has been made. Now is the right time to work together on defining an action plan to :

- Clarify what works well and what needs to be improved in the current coverage schemes and political initiatives. Indeed, as indicated before, the mere existence of scheme(s) or initiative(s) is not automatically a guarantee of improved/faster access given that some of these schemes/initiatives might not be appropriately designed, implemented or administrated
- Identify the reasons behind these successes and shortcomings,
- Establish best practices for developing, implementing and running optimal/adequate scheme(s) or initiative(s) for improved/faster patient access to innovative medical procedures and technologies.

MedTech Europe is calling on all key European decision-makers including policy-makers, national and regional payers having responsibilities in this area to join this endeavour. It is crucial to ensure a commitment to safeguarding reimbursement and equitable patient access to innovative value-added digital health technologies, medical devices, and *in vitro* diagnostics. Therefore, it is crucial to implement throughout all European countries holistic pathways which are appropriate to medical technologies, reward their reimbursement and funding in line with the value provided and ensure their uptake.

INITIATIVES TO TRANSFORM HEALTH CARE SYSTEMS

An overarching barrier to patient access to medical technologies is the limited political commitment to change healthcare (medical technology) funding. However, some European countries are conducting/are planning to conduct concrete/tangible political initiatives/actions aimed at transforming their health care systems and funding and reimbursement of all digital health technologies, medical devices, and IVDs and combinations thereof in all European countries. Activities or discussions about transforming the healthcare system include financing, coverage landscape, and health technology assessment aspects of market access. These (ongoing and planned) initiatives/actions are listed below but the evaluation of their impact on the systems was out of the scope of the project. Therefore, as indicated before, the mere existence of an initiative is not automatically a guarantee of improved/faster funding/reimbursement.

This section can be useful for understanding the future directions for the development of the healthcare systems in Europe in relation to medical technologies and procedures. In total, 33 ongoing initiatives to transform health care systems were identified from the screening in 32 countries. The scope of the initiatives varied from the reform of the procedure coding systems in Belgium and Italy to the introduction of the novel payment system in Switzerland. The largest number of initiatives was identified in the UK (n=6, including two initiatives related to England only and one related to Scotland only), Belgium (n=4), France, and Italy (n=3 each). Other countries with identified initiatives include the Czech Republic, Denmark, Estonia, Finland, Germany, Greece, the Netherlands, Norway, Poland, Portugal, Slovakia, and Switzerland. One initiative relates to the Nordic region (relevant to five countries, including Denmark, Finland, Iceland, Norway, and Sweden).

NB! Please, note that this section is completely independent of the sections above and below (Appendices 2 and 3) with the specifics of the innovative payment schemes in Europe. This section represents the results of the additional work, separate from the overview of the innovative payment schemes.

The selection of the activities was performed in the period of June-September 2022. Please, note that in relation to digitalisation activities in the healthcare system, only initiatives with concrete/tangible actions (e.g., the establishment of the novel payment scheme for digital technologies, etc.) were considered in the list of ongoing initiatives. Initiatives at the "intention" level or high-level documents (including strategies for the development of IT in healthcare and the healthcare system in general) were not included.

The list of identified activities is provided in the table below.

Country	Organisation	Title	Brief overview	Link
Belgium	INAMI/RIZIV	Structural reform of the INAMI/RIZIV Nomenclature	INAMI/RIZIV Nomenclature represents the key payment mechanism for physician services on a fee-for-service basis in Belgium. The reform was launched in 2019, and its completion is scheduled for 2024. The objective is to develop a new logic and structure to the current Nomenclature, also toward international standardization. Multiple changes are planned, including the following: • Update and adapt the Nomenclature to changes in medical activity and new care models (telemedicine, multidisciplinary care, etc.); • Introduce incentives to promote collaboration and quality; • Distinguish "medical fees covering all the costs directly or indirectly linked to the performance of medical services and not covered by other sources" from the " fees covering the services of the doctor” The project comprises 3 phases: • Phase 1: restructure and adapt the wording of the services; New common classification for medical-surgical technical procedures is in the finalization stage; the radiotherapy sector requires a major reform of its structure • Phase 2.1: to determine the relationship between the different services based on objective criteria (professional part of the fees); • Phase 2.2 assess the operating costs necessary for the implementation of health services Phases 2.1 and 2.2 started in March 2022, and the completion is scheduled for December 2024.	Link

Country	Organisation	Title	Brief overview	Link
Belgium	Federal Public Service (FPS) Public Health / INAMI-RIZIV	Integrated care plan	FPS Public Health is currently changing the way of organizing and delivering care towards integrated care: cross-functional collaboration, continuity of care, and patient orientation. The development interfederal Integrated Care plan was launched in June 2022. The development will be based on multiple existing projects at the national and regional levels. For example, pilot projects for integrated care for the chronically ill can be found here. FPS Public Health, INAMI/RIZIV, and WeCare (external partner) will work closely together. The completion is expected in 30 months.	Link

Belgium	Minister of Social Affairs and Public Health	Reform of the organisation and financing of hospitals	In January 2022, Federal Minister of Health Frank Vandenbroucke presented his hospital reform project.
			
			The main points are the following:
			• More efficient collaboration between hospitals, particularly through locoregional/supra-regional networks. The federated entities will soon approve 23 hospital networks
			• The financing of hospitals will be simplified toward an "all-in" DRG package per pathology by 2024.
			• A step towards bundled payment per care pathway, of which the DRG all-in package is part. DRG all-in packages will comprise the following:
			  ○ Care-related sub-sections included in the hospital budget (Budget des Moyens Financiers, BMF)
			  ○ Drugs
			  ○ Medical devices
			  ○ Operating costs for medical services
			  ○ In the long term, the inclusion of pre- and post-hospitalisation
				Link

Country	Organisation	Title	Brief overview	Link
			○ Data collection is scheduled for 2022 and 2023, and the development of packages for 2024 • A step towards bundled payment considers the introduction of funding models that aim for continuity, coordination, and integration of care in the context of the growing prevalence of chronic diseases ○ In the long term, the funding will be made per care pathway and per pathology, of which the DRG all-in package is a part ○ There is the ongoing development of care pathways (e.g., for obesity, diabetes, long COVID, perinatal care, pulmonary, rehabilitation, pre and post-transplantation of abdominal organs, psychiatric care) • Particular attention to laboratories and medical imaging. The model is no longer: "the more examinations, the more money" but "pay correctly according to what is necessary for the patient". Financing by pathology for laboratories. Reimbursement for an average number of scans, depending on the size of the infrastructure, and no longer per scans performed. • Reduce unnecessary hospital stays and promote day hospitalisations. Encourage the implementation of innovative technologies • Reform of the Nomenclature • Value-based purchasing: increase current financial incentives for quality, and focus on the health care objectives • Reducing fee supplements. From 2024, the calculation of fee supplements will be capped only on the professional part of the fees Implementing the reform will take several years and is expected to be completed by 2025. The basic elements of the reform will be laid in	

Country	Organisation	Title	Brief overview	Link
			2022-2023-2024 and could be implemented in 2025. In 2022-2023, the first achievements will already be made in terms of clinical biology, medical imaging, day hospitalisation, and quality financing. The hospital networks will be developed in stages, with the definition of local and supra-regional care missions in 2022.	
Belgium	Federal Public Service (FPS) Public Health	Data for better health	An initiative of the federal minister of Public health, the federal minister of Digital Agenda, and the federal Secretary of state Privacy, supported by Sciensano, NIDO (the innovation lab of the Federal Government), and DigitYzer. An initiative aims to identify existing obstacles to FAIR (Findable, Accessible, Interoperable, and Re-usable) data policy in public health and to formulate, test, and implement solutions to achieve an integrated data access policy. The datasets currently available to governments and mutuality funds will be accessible to the industry so that marketing dossiers can be established quickly and efficiently.	Link
Czech Republic	The Institute of Health Information and Statistics of the Czech Republic (ÚZIS ČR)	Development of the classification of hospitalisation procedures	Currently, the List of Health Services (SZV) acts as a positive list of reimbursed services. It is used for outpatient (fee for service) reimbursement but is also used for coding hospital services in the CZ-DRG system (in 2022, v4 of CZ-DRG was used; in 2023, v5 of CZ-DRG, revision one, will be used). However, the Central Institute of Health Information and Statistics (ÚZIS) has been working on the development of a novel Classification of Hospitalisation Procedures (Klasifikace hospitalizačních procedur) since 2015. This is because the List of Health Services (SZV) lacks most of the basic classification properties (e.g., the procedures are not grouped for individual organs/systems (according to anatomical principle), there is no standardized description of medical	Link

Country	Organisation	Title	Brief overview	Link
			interventions, etc.). These properties will be implemented in the new classification. The structure of the new Classification of Hospitalisation Procedures summarizes the features of the French classification of medical procedures (CCAM), Slovak List of health services (ZZV), Nordic Classification of Surgical Procedures (NOMESCO NCSP+), and American Procedure Coding System (ICD 10 PCS). The time schedule for implementation of the novel Classification of Hospitalisation Procedures has not been defined yet.	
Denmark	Danish Health Technology Council	Work plans for the Treatment Council	The Treatment Council is expected to prepare 15-25 evaluations annually. The evaluations will be carried out for new and existing equipment and health technologies. Both private actors and public individuals can nominate proposals for evaluation. In addition to evaluations, the Treatment Council is also expected to carry out 2-3 major analyses annually. The analyses may be based on more fundamental questions about treatment regimens or approaches to or organisation of treatments. Contrary to the evaluations, only hospital management and regions, including regional councils, can nominate proposals for themes for analyses. The Treatment Council may also propose themes for the analyses.	Link
England	NHS England / Accelerated Access Collaborative	The NHS Innovation Service	In late June 2022, Accelerated Access Collaborative launched a new NHS Innovation Service aimed at supporting the spread of promising and impactful innovations. It is an online service for health innovators (individuals and companies) providing tailored and coordinated support or advice for "adoption-ready" products. The service will help innovators to understand the regulations and standards they need to meet, the evidence they should demonstrate, and the NHS procurement and reimbursement processes.	Link

Country	Organisation	Title	Brief overview	Link
			Innovators using the service may receive help from all 15 Academic Health Science Networks (AHSNs) and nine national organisations, including NICE, the Medicines and Healthcare Products Regulatory Agency (MHRA), National Institute for Health and Care Research (NIHR), Scottish Health Technologies Group (SHTG), Health Technology Wales (HTW), and NHS Supply Chain. The NHS Innovation Service will replace the HealthTech Connect platform and is currently in public beta – a public testing phase.	
England	NHSX, NICE	Multi-agency advisory service (MAAS) for artificial intelligence and data-driven technologies	The NHSX (NHS AI Lab) has funded the creation of the MAAS. The launch is scheduled for early 2023. MAAS is a collaboration between four organisations: NICE, the Care Quality Commission (CQC), the Medicines and Healthcare Products Regulatory Agency (MHRA), and the Health Research Authority (HRA). This new cross-regulatory service will be a "one-stop-shop" for support, information, and guidance on the regulation and evaluation of AI technologies.	Link Link
Estonia	Estonian Health Insurance Fund	Health system development projects	The Estonian Health Insurance Fund (EHIF) provides grants for projects that present innovative service models, the goals of which are to improve health outcomes and quality of care, improve the treatment pathways, as well as to support the patients requiring care, and to improve prevention methods. The projects are paid from the Innovation Fund of the EHIF. The largest project is the stroke pathway project, which aims to provide integrated care for this condition to the patient. The next large expected project will be regarding endoprostheses. Furthermore,	Link

Country	Organisation	Title	Brief overview	Link
			there other minor projects are still ongoing, mostly related to remote monitoring. The services that are a part of the project are listed in § 81 of the Estonian List of Services. These services will be reimbursed for a limited period of time, during which the economic and clinical evidence will be collected. Once the initial coverage period has expired, the EHIF experts will develop a report on the topic, upon which the decision on regular reimbursement will be made.	
Finland	Finnish Government	Reform of healthcare, social welfare, and rescue services	The organisation of public healthcare, social welfare, and rescue services will be reformed in Finland. The responsibility for organizing these services will be transferred from municipalities to well-being services counties from 2023. The key objective of the reform is to improve the availability and quality of basic public services throughout Finland. The highest decision-making power in each well-being services county will be exercised by a county council, whose members and deputy members will be elected in county elections. The responsibility for organizing health, social, and rescue services will be transferred from municipalities to well-being services counties from the beginning of 2023. Municipalities will remain responsible for promoting the health and well-being of their residents. The public sector will remain the organizer and primary provider of services. Private sector actors and the third sector will supplement public health and social services. Five collaborative areas for healthcare and social welfare will be created to secure specialized services.	Link
France	Ministry of Health and Prevention	Reform of the reimbursement of	Since coming into force Article 36 of the Social Security Financing Act for 2022 on July 1, 2022, remote medical monitoring, including medical surveillance by the remote monitoring operator (medical part) and digital medical devices for remote monitoring (digital part), is	Link

Country	Organisation	Title	Brief overview	Link
		telemonitoring and remote monitoring	reimbursed under statutory health insurance according to the conditions defined in the Article 36. To obtain reimbursement under statutory health insurance, remote medical monitoring (the analysis of data and the alerts transmitted using a digital medical device) must be assessed by the CNEDiMTS for the existence of "an improvement in medical care" either in relation to care without remote monitoring or in comparison with remote monitoring activities which are already covered. If the assessment by the CNEDiMTS concludes that there is an improvement in medical care, the remote medical monitoring services will be registered in a special list (called "telemonitoring list"), separately from the LPPR. The list will specify the indications of the remote monitoring services eligible for reimbursement. The registration of the digital medical device in the list will be carried out in the form of a reference system proposed by the HAS. In 2022, the HAS published reference frameworks for remote medical monitoring in five disease areas covered by the ETAPES program (diabetes, chronic kidney failure, chronic respiratory failure, chronic heart failure, and implantable cardiac prostheses for therapeutic purposes). The registration of medical devices can be performed via a generic description defined in the repository or by brand name (if the medical device is not covered by the repository). The remote medical care will be reimbursed in the form of a fixed package split into two lump sums: for reimbursement of the healthcare professional providing remote medical surveillance and for reimbursement of the operator or distributor of a digital medical device. 100% of the remote monitoring package amount will be covered by statutory health insurance. The actual reimbursement (lump-sum amounts and conditions of reimbursement) will be implemented by the Decree of the Council of State; however, it has not been published as of September 1, 2022.	

Country	Organisation	Title	Brief overview	Link
			The devices with remote monitoring functions will be reimbursed if they are registered in the new specific list with a fixed maximum tariff. Ministers of the Economy, Health, and Social Security will publish the Decree that defines the maximum tariff of digital medical devices for remote monitoring and associated collection accessories. This maximum price will include the applicable taxes. However, it has not been published as of September 1, 2022. The complexity of the new regulation required an in-depth phase of preparation, and consultations did not make it possible to maintain the initially planned timetable. Despite the end of the ETAPES program having been scheduled for August 1, 2022, the financial support for the ongoing experiments under the ETAPES program will be maintained until the publication of the Decree of the Council of State (with reimbursement tariffs and conditions), but no later than December 31, 2022.	
France	Ministry of Health and Prevention	Early Coverage framework for innovative digital medical devices	To facilitate access to the market for innovative digital medical devices without the evaluation of Actual Benefit (SA) and Added Clinical Value (ASA) by the CNEDIMTS, the new Article L. 162-1-23 of the 2022 Social Security Financing Act introduces a system of early coverage for digital medical devices for therapeutic purposes or digital medical devices for remote medical monitoring for a non-renewable period of one year (Early Coverage framework). This procedure is different from the innovation package (forfait innovation) and the transitional coverage (prise en charge transitoire). To obtain reimbursement under the Early Coverage framework, a digital medical device must meet the following criteria: • To be innovative, particularly in terms of clinical benefit or improvement of the organisation of care, based on the first data available and taking into account any relevant comparators (defined by CNEDiMTS); • To be CE marked for the indication in question;	Link

Country	Organisation	Title	Brief overview	Link
			• Comply with the regulations relating to the protection of personal data as well as the applicable interoperability and security standards; • Allow the processed data to be exported in interoperable, appropriate formats guaranteeing direct access to the data, and include, where appropriate, interfaces allowing the exchange of data with devices or accessories for collecting the patient's vital parameters. The reimbursement under the Early Coverage framework can be requested by the operator (i.e., manufacturer/distributor) of a digital medical device (defined in Article 36 of the Social Security Financing Act for 2022). The reimbursement will be granted on a fixed basis (a lump sum). A Decree of the Council of State will define the amount of the lump sum and conditions of reimbursement (which has not been published yet). This framework cannot be combined with any other mode of coverage (neither registration on the LPPR, the intra-GHS list, or innovation package, nor with reimbursement for hospitalisation services via DRG). The duration of reimbursement under the Early Coverage framework is one year; the period is non-renewable. The operator (i.e., manufacturer/distributor) of a digital medical device is obliged to apply for inclusion in the LPPR within six months (for digital medical devices with therapeutic function) or to the "telemonitoring list" within nine months (for digital medical devices with remote monitoring function).	
France	High Council of Nomenclatures (HCN) / Ministry of Health and Prevention	Revision of the CCAM Classification	The High Council of Nomenclatures (HCN) was established in 2021, and one of its goals is to work on the revision of the CCAM Classification of procedures. The objectives of the revision are: • Improvement of the descriptive nature of the services and their relevance;	Link

Country	Organisation	Title	Brief overview	Link
			• Introduce missing, new services, taking into account recent innovations; • Simplification of the classification by removing obsolete acts (with the potential reorganisation of the services). The revision process is expected to last five years.	
Germany	Federal Ministry of Health (BMG) / Federal Institute for Drugs and Medical Devices (BfArM)	Ordinance on the Eligibility for Reimbursement of Digital Nursing Applications (VDiPA)	On June 9, 2021, the Law on Digital Modernization of Healthcare and Nursing (Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz, DVPMG) came into force. Among others, the DVPMG creates the necessary legal requirements and incentives for reimbursement of digital nursing care applications (DiPAs) [to be prescribed by the providers of remedies and midwives] in the same manner as digital health applications (DiGAs) The assessment pathway is expected to be quite the same as for DiGAs; DiPAs that will successfully pass an assessment of the BfArM will be listed in a newly created directory of reimbursable digital nursing applications (DiPA directory) Details of this assessment and the DiPA directory will be regulated by a supplementary legal ordinance of the Federal Ministry of Health (BMG), the Ordinance on the Eligibility for Reimbursement of Digital Nursing Applications (VDiPA) Similar to DiGAs, the BfArM is preparing a supplementary comprehensive guide and an application portal, which were expected to be published at the end of the third quarter of 2022. As soon as the application portal is online, corresponding applications can be submitted via this portal. It will not be possible to submit any applications outside this application portal	Link Link

Country	Organisation	Title	Brief overview	Link
Germany	National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)	Pilot project genome sequencing	The basis of the model project is the extensive genome sequencing as part of a structured clinical treatment process and the resulting data merging of clinical and genomic data in a data infrastructure that facilitates an analysis of the data obtained to improve medical care. The model project will start in January 2023 and must run for at least five years The model project is to be carried out uniformly throughout Germany. For this purpose, a uniform contract for the implementation of the model project according to § 64e paragraph 1 sentence 1 SGB V must be concluded by January 1st, 2023	Link
Greece	Greek DRG Institute (KETEKNY)	Introduction of a novel DRG system	A new DRG system is to be implemented, updating the current KEN-DRG system. The Greek DRG Institute (KE.TE.K.N.Y.) is the body in charge of the development of the new Greek DRG system. The new DRG system will be based on the German DRG system. The Greek DRG Institute (KE.TE.K.N.Y.) and German DRG administrator InEK are working together on implementation, which started in 2019. The European Union funds the project. The Ministry of Health launched pilots in 20 public hospitals and seven private clinics, where the DRG system will be introduced, tested and refined. As of June 2022, the new DRG system is in pilot use in the Crete region (4/55 Greek prefectures). From 2023, the new Greek DRG (Gr-DRG) system is expected to be officially implemented in Crete and some other prefectures.	Link
Italy	Ministry of Health	National HTA program for medical devices	The National HTA program for medical devices was published in September 2017. An agreement on the national HTA program for medical devices has been reached between the central and regional authorities. The main player in this context will be the Cabina di Regia per l'HTA, a national steering committee for HTA created in 2015-2016 by the Ministry of	Link

Country	Organisation	Title	Brief overview	Link
			Health, including representatives of the Ministry of Health, four Regions, the national agency for regional healthcare (AGENAS), and the Italian Drugs Agency (AIFA). The steering committee (CdR) will coordinate the activities of the program. The deliverables will be disseminated among all the decisional levels of the national healthcare system, from the national commission for the essential level of care (Commissione Nazionale LEA) to the regional directorates that will circulate them across hospitals and regional procurement units. Despite the open possibility for suggesting technologies, there is no information on the actual work being done or the outcomes/consequences of the assessments.	
Italy	Ministry of Health / AGENAS	Introduction of a novel DRG system	In 2015, the Ministry of Health officially presented a new project called "It.DRG project", the goal of which is to develop a de novo (completely new) Italian DRG system. However, the project was already conceived in 2004 and initiated in 2011. The project is led by the Ministry of Health and the Emilia Romagna region. The National Agency for Regional Healthcare Services (AGENAS) is a technical partner of the program. There are four consists of four activities: • Implementation of a new diagnosis coding system (ICD-10; responsibility of Friuli Venezia Giulia region); • Development of a new procedure coding classification (CIPI; responsibility of Lombardy region and AGENAS) • Development of new It.DRG groups (responsibility of Emilia Romagna region);	Link

Country	Organisation	Title	Brief overview	Link
			• Development of cost-weights (responsibility of the Ministry of Health). In January 2022, a consultation was launched, in which the interested parties could have submitted their comments regarding the new procedure coding nomenclature that would be used in the de novo DRG system (Italian system of coding and classification of surgical interventions and diagnostic and therapeutic procedures, CIPI).	
Italy	Regional health authority of the Tuscany region	Development of criteria of innovativeness of medical technologies	In July 2022, the regional criteria for the innovativeness of medical technologies were established. Innovative technologies must undergo health technology assessment prior to the decision to procurement decision. Innovative technologies should be priorities for HTA.	Link
Netherlands	Dutch Healthcare Authority (NZa)	Integrated funding for maternity care	In a number of regions, healthcare providers and health insurers are making agreements about integrated funding for maternity care. This can be done on the basis of the Integrated Birth Care Policy Rule (BR/REG-22100) of the Dutch Healthcare authority. Integrated funding should remove barriers in funding that make cooperation between primary care (midwives and maternity nurses) and secondary care (gynaecologists) more difficult. After the adoption of the Policy Rule in 2017, the experiment on integral funding of maternity continued until January 1, 2022. Since 2022 the experiment under the Integrated Birth Care Policy Rule became a part of the regular funding. From January 2023, the two-track policy for funding maternity care will apply: this means that the integrated funding is an addition to the existing monodisciplinary funding.	Link

Country	Organisation	Title	Brief overview	Link
			The new funding model should be adopted by 2028 at the latest (NZa advice of September 2020).	
Nordic region	N!P, Nordic Innovation	NordDEC: Cross-Border Digital Health Framework Programme	The Nordic Digital Health & Medication Platform project aims to establish a system for healthcare providers to evaluate and identify trusted digital health technologies within healthcare and preventive care. It also aims to provide product developers and owners with clear visibility of what good looks like in order to inform product development, market access strategies, and commercial positioning. Drawing from international best practices, it will establish a common benchmark of criteria across the region, offering the ability to simply layer-on local requirements while using size and scale to attract inward investment into the Nordic nations.	Link
Norway	Directorate of Health, Directorate of eHealth, Norwegian Health Network	Safer health apps	The project by the Directorate of Health, Norwegian Health Network, and the Directorate for e-Health promotes the development and use of apps and mobile health technology with good quality. In early 2022, the project was piloting a newly developed evaluation framework (a component of a national model for quality assurance and access to health apps). The following changes are planned based on the pilot project outputs: • The evaluation framework developed by the project will be used for certification and making health apps available (at the Helsenorge tool catalogue) • The Directorate of e-Health, the Directorate of Health, and the Norwegian Health Network will establish a joint body - led by the Directorate of e-Health - to oversee the operational management of the national model for quality assurance and access to health apps	Link

Country	Organisation	Title	Brief overview	Link
			• The Directorate of e-Health will launch the new project to establish management of the evaluation framework and the national model for quality assurance and access, including funding, establish criteria for which apps can be certified and awarded the quality mark, improve the availability of health apps for citizens and health professionals, and other objectives. A "library" of apps that is quality assured by the authorities can also be exposed on sites other than Helsennorge	
Norway	"New Method"	New prioritisation criteria for the evaluation of medical technologies and procedures	"New method" evaluates three types of treatment methods: 1) Drugs; 2) Non-pharmaceutical technologies (medical devices, equipment, and in-vitro diagnostic and genetic tests; 3) medical procedures and organisational measures. For now, there are no clear prioritization criteria for selecting methods other than drugs for evaluation within the "New Method" framework. In January 2021, the Ordering Forum of "New Method" commissioned the project to develop prioritisation criteria for which methods other than drugs shall be prioritised for assessment within the Framework at the national or local levels. Two groups were created to work on the project. The main group consists of the National Institute of Public Health (NIPH), the regional health authorities (RHA), Hospital Procurement HF, Melanor (industry association), the Secretariat of the "New Method" and others; the internal group consists of NIPH, Hospital Procurement HF, and Secretariat. On June 24, 2022, the status of the assignment was updated. The Secretariat for "New Methods" is working with NIPH on a memorandum that will provide proposed prioritisation criteria. The memorandum was expected to be sent to the MOH on October 01, 2022.	Link

Country	Organisation	Title	Brief overview	Link
Poland	National Health Fund	Project "Implementation of the Hospital-Based HTA (HB-HTA) - Hospital Assessment of Innovative Medical Technologies"	The practical goal of the Project was to implement the hospital-based medical technology assessment (Hospital-Based HTA - HB-HTA) methodology), serving to increase the possibilities of managing the health care system at the local level (hospital directors) and (indirectly) at the national level. The model, strategy, and methodology of the HB-HTA (infographics) were published at the end of June 2022.	Link
Portugal	Presidency of the Council of ministers	New Statute of the National Health Service	The new NHS statute was approved in July 2022 and published on August 4, 2022, and it replaces the one that has been in force since 1993. It is centred on better organisation and more autonomy of the stakeholders in the system. It is considered that the new NHS statute will give more autonomy to hospitals and health centres, not only in hiring but also in investment.	Link
Scotland	NHS Scotland	Accelerated National Innovation Adoption (ANIA) Pathway	The new pathway in Scotland was announced in July 2022. It aims at fast-tracking the adoption of proven technological innovations across NHS Scotland. ANIA will ensure the quick and safe rollout of technological innovations that will improve patient outcomes, reduce waiting times and improve patient and staff experience. The ANIA pathway is designed to: • Identify, assess, and implement technological innovations on a Once for Scotland basis. • Ensure that only the highest impact, evidence-based innovations that are aligned with Scottish Government priorities are adopted nationally. • Support ANIA partners in sharing their expertise to drive high-impact innovations along the ANIA pathway at an accelerated pace.	Link

Country	Organisation	Title	Brief overview	Link
			• Enable joint planning with territorial NHS Boards for accelerated adoption and implementation of innovations and associated service change requirements. As operational details of the scheme are not available at the time of writing the report, it is included in the list of ongoing initiatives. It should be transferred to the list of active schemes in future versions of the report	
Slovakia	Ministry of Health of the Slovak Republic	National Institute for Health Technology Assessment	The legislation setting the legal foundations for the new, independent HTA agency was published in the spring of 2021. The National Institute for Health Technology Assessment was established in 2022. It will address technologies that should be reimbursed by Statutory Health Insurance, with a budget impact higher than € 1.5 million per year. Initially, the focus will be on pharmaceuticals, but the work can potentially be extended to medical technologies as well.	Link
Slovakia	Centre for Classification System (CKS DRG)	Expansion of the DRG system to cover services provided in day-case settings (JSZ)	The Steering Committee of the CKS DRG was requested to prepare a proposal for the expansion of the DRG system to cover services provided in day-case settings (JSZ). The work is being conducted by the Day-Case Working Group of the CKS DRG. The process was initiated on September 9, 2022. The proposal was submitted to the Steering Committee on October 17, 2022.	Link
Switzerland	ATS TMS	Introduction of the novel payment system in out-patient care, TARDOC	A new entity, ATS-TMS AG, was founded in 2016 by the hospitals' association (H+), the medical tariff commission (MTK/CTM), the association of physicians (FMH), and curafutura (association of insurance companies) to develop a thoroughly revised tariff structure for ambulatory medical benefits, as the currently used one (TARMED) is considered obsolete.	Link

Country	Organisation	Title	Brief overview	Link
			The new outpatient reimbursement system is called TARDOC. The ATS-TMS AG has submitted the TARDOC system to the Swiss Federal Council for approval several times, but the proposals have been rejected as they did not meet the legal requirements, in particular cost neutrality. The ATS-TMS AG is now working on improving the system, and the introduction of the TARDOC reimbursement system is expected no earlier than January 2024.	
Switzerland	Solutions Tarifaires Suisses (STS)	Lump-sum (DRG) payment system for outpatient surgery	In June 2020, santésuisse (the leading organisation of Swiss health insurers) and the Swiss Society of Surgeons (FCMH) submitted a proposal to the Federal Council for the acceptance of 67 lump-sum payment packages for out-patient services. The lump-sum payment packages concern the following areas of care: hand surgery, radiology (MRI / CT), pediatric surgery, vascular medicine, eye surgery, and anaesthesia. In 2021, a new entity that was tasked with the development of the outpatient DRG system, the Solutions Tarifaires Suisses (STS), was established by santésuisse (the leading organisation of Swiss health insurers), the Swiss Society of Surgeons (FCMH), and the Swiss Hospitals' Association (H+). Implementation of the new payment system is expected in 2024.	Link
UK	Department of Health and Social Care	Genome UK: shared commitments for UK-wide implementation 2022 to 2025	The shared commitments of the UK government, Welsh and Scottish Governments, and Northern Ireland Assembly built on the vision outlined in Genome UK in 2020. New' shared commitments' set out priority actions for genomics initiatives across the UK. Cancer diagnosis, earlier detection of diseases, and patient access to clinical trials will improve. Plans will	Link

Country	Organisation	Title	Brief overview	Link
			advance the government's priorities to reform healthcare and make the UK a scientific superpower.	
UK	NICE, Medicines and Healthcare products Regulatory Agency (MHRA), Health Technology Wales, Scottish Health Technologies Group	Innovative Devices Access Pathway	The project will research, design, and scope an innovative access pathway for selected medical and digital health technologies that are new and innovative, meet critical unmet needs in the health and care system, and have the support of an NHS organisation or network to meet relevant safety standards. This is a joint project of NICE, Medicines and Healthcare products Regulatory Agency (MHRA), Health Technology Wales and Scottish Health Technologies Group.	Link
UK	NICE	Early Value Assessment program for MedTech	NICE is starting a novel health technology assessment program with a focus on innovative technologies with an emerging evidence base. The focus of the program is on the rapid assessment of digital products, devices, and diagnostics for clinical effectiveness and value for money. The first two pilot digital health topics began their early value assessments in June 2022 with a view to publishing findings in October. The objective of the program is to inform commissioners and providers about the value of medical technologies in an expedited way.	Link

APPENDIX 1 – LIST OF MONITORED ORGANISATIONS

The table below includes the list of organisations from 32 countries which have been used for website screening to identify relevant innovative payment schemes and ongoing initiatives to transform the healthcare system (including reimbursement and funding systems).

Country	Stakeholder
Austria	Federal Ministry for Social Affairs, Health, Care and Consumer Protection (BMSGMK)
Austria	Main Association of Austrian Social Insurance Institutions (HVB)
Austria	Austromed
Belgium	Federal Public Service Public Health
Belgium	National Institute for Health and Disability Insurance (INAMI-RIZIV)
Belgium	mHealthBelgium
Belgium	beMedTech
Bulgaria	Ministry of Health
Bulgaria	National Health Insurance Fund (NZOK)
Croatia	Ministry of Health
Croatia	Croatian Health Insurance Fund (HZZO)
Cyprus	Ministry of Health
Cyprus	Health Insurance Organisation (GESY)
Czech Republic	Ministry of Health
Czech Republic	Association of Health Insurance Companies of the Czech Republic (SZPCR)
Czech Republic	CzechMed
Denmark	Danish Health Authority (SST)
Denmark	Danish Regions
Denmark	Danish Health Technology Council
England	Department of Health and Social Care
England	NHS England and NHS Improvement (NHSEI)
England	NHS Accelerated Access Collaborative (AAC)
England	National Institute for Health and Care Research (NIHR)

Country	Stakeholder
England	NHSX (now part of NHS Transformation Directorate)
England	Association of British HealthTech Industries (ABHI)
Estonia	Ministry of Social Affairs
Estonia	Estonian Health Insurance Fund
Finland	Ministry of Social Affairs and Health
Finland	The Social Insurance Institution of Finland (Kela)
Finland	SAILAB – MedTech Finland
France	Ministry of Health and Prevention
France	High Authority for Health (HAS)
France	Union of the In Vitro Diagnostics Industry (SIDIV)
France	National Union of Medical Technology Industry (SNITEM)
Germany	Institute for the Hospital Remuneration System (InEK)
Germany	Federal Joint Committee (G-BA)
Germany	Federal Ministry of Health (BMG)
Germany	Federal Institute for Drugs and Medical Devices (BfArM)
Germany	National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)
Germany	German Medical Technology Association (BVMed)
Germany	German Industry Association for Optics, Photonics, Analytical and Medical Technologies (Spectaris)
Greece	Ministry of Health
Greece	National Organisation for the Provision of Health Services (EOPYY)
Hungary	State Secretariat for Health
Hungary	National Health Insurance Fund (NEAK)
Hungary	National Directorate General of Hospital (OKFŐ)
Iceland	Ministry of Health
Iceland	Icelandic Health Insurance
Ireland	Department of Health

Country	Stakeholder
Ireland	Health Service Executive
Italy	Ministry of Health
Italy	Superior Health Institute (ISS)
Italy	Lombardy region
Italy	Emilia Romagna region
Italy	Veneto Region
Italy	Tuscany region
Italy	Lazio region
Italy	Confindustria Dispositivi Medici
Latvia	Ministry of Health
Latvia	National Health Service
Liechtenstein	Public Health Office (AG)
Lithuania	Ministry of Health
Lithuania	National Health Insurance Fund
Luxembourg	Ministry of Health
Luxembourg	Ministry of Social Security
Luxembourg	National Health Insurance (CNS)
Malta	Ministry for Health
Netherlands	Dutch Healthcare Authority (NZa)
Netherlands	Dutch Healthcare Institute (ZIN)
Netherlands	Dutch Organisation for Health Research and Development (ZonMw)
Netherlands	Dutch Association of Health Insurers (ZN)
Netherlands	Interest group of manufacturers, importers, and traders of medical devices and medical technology (NEFEMED)
Northern Ireland	Department of Health
Northern Ireland	Health and Social Care Northern Ireland

Country	Stakeholder
Norway	Ministry of Health and Care Services
Norway	Norwegian Directorate of Health
Norway	Norwegian Directorate of eHealth
Norway	Norwegian Health Economics Administration (Helfo)
Poland	Ministry of Health
Poland	National Health Fund (NFZ)
Poland	Agency for Health Technology Assessment and Tariff System (AOTMiT)
Portugal	Ministry of Health
Portugal	National Health Service (SNS)
Portugal	National Authority of Medicines and Health Products (INFARMED)
Romania	Ministry of Health
Romania	National Health Insurance House (CNAS)
Scotland	Department of Health and Social Care
Scotland	NHS Scotland
Scotland	National Services Scotland
Slovakia	Association of Health Insurance Companies of the Slovak Republic (AZPSR)
Slovenia	Ministry of Health
Slovenia	Slovenian Health Insurance Fund (ZZZS)
Spain	Ministry of Health, Consumer Affairs, and Social Welfare
Spain	Inter-territorial Council of National Health System (CISNS)
Spain	Spanish Federation of Healthcare Technology Companies (FENIN)
Spain	Catalonia autonomous community
Spain	Madrid autonomous community
Spain	Andalusia autonomous community
Spain	Basque Country autonomous community
Spain	Catalan Health Institute (ICS)
Spain	Basque Health Service (Osakidetza)

Country	Stakeholder
Spain	Institute of Health Carlos III (ISCIII)
Sweden	National Board of Health and Welfare (Socialstyrelsen)
Sweden	Swedish Municipalities and Regions (SKR)
Sweden	Stockholm region
Sweden	Skåne region
Sweden	Västra Götaland region
Sweden	Örebro region
Sweden	Dental and Pharmaceutical Benefits Agency (TLV)
Sweden	Council for New Therapies (NT-rådet)
Sweden	Medical Technology Product
Switzerland	Federal Office for Public Health (FOPH)
Switzerland	Health Insurer Association santésuisse
Switzerland	Health Insurer Association curafutura
Wales	Department of Health and Social Services
Wales	NHS Wales

APPENDIX 2 – EXCLUDED SCHEMES

The table below includes different research, financing, and other schemes and activities, which were initially considered for inclusion in the report, but considered ineligible after a careful analysis based on the scope of the project, which was conducted using the set of exclusion criteria (as defined on page 16).

There was no intent to create an exhaustive list of the schemes not matching the inclusion criteria established for this project (as per definition, these schemes are outside the scope of the project). It was, however, decided to list these "not matching the inclusion criteria" schemes in the present Appendix.

Country	Framework	Rationale
Belgium	Reimbursement of certain medical care via INAMI/RIZIV Conventions	Certain types of care in Belgium are not reimbursed via INAMI/RIZIV Nomenclature and Lists of Reimbursable Devices but via specific regulations (contracts, called Conventions) by INAMI/RIZIV. It can cover a broad range of topics, from NGS testing to diabetes care. These contracts are considered a part of the standard reimbursement framework and therefore were not relevant to the scope of the project.
England	Rapid Uptake Products and Pathway Transformation Fund	The Rapid Uptake Products framework does not provide any financial support but indeed aims to support the introduction of selected products. Pathway Transformation Fund provides funding for training of staff, pathway re-design, and covering double running costs. However, the products themselves do not receive any funding. Therefore, this program was not relevant to the scope of the project.
England	NHS Innovation Accelerator (NIA)	The Accelerator is an entity within NHS England and not a program. It has some direct means of supporting small-scale medical start-ups via fellowship mechanisms and some others (education, networking with Academic Health Science Networks), but it is not relevant in the scope of the report.
England	NHS Insights Prioritisation Programme (NIPP)	This program represents an applied research activity. It aims at testing different technologies and organisational methods and generation of rapid insights/conclusions to enable the decision-making of NHS stakeholders. The program does not qualify for the inclusion criteria.
England	Elective recovery tech fund	A large fund with the objective to accelerate the uptake of digitally supported care in planned, or "elective", care pathways. Typically, it focuses on general IT solutions, including those for keeping patient records, streamlining administrative processes, etc. It relates more to the procurement process than to an instrument for the support of medical innovations. Therefore, this activity was not relevant to the scope of the project.
England	Unified Tech Fund	The fund does not represent a specific payment mechanism. It is simply a single repository of all ongoing funding initiatives in the digital space in

Country	Framework	Rationale
		England. Procurement activities and frameworks are outside the scope of the project.
England	Adoption Fund	The Adoption Fund was commissioned by NHS England to support Integrated Care Systems (ICSs) in introducing or scaling up digital innovations in elective care pathways. The program did not provide temporary reimbursement or funding but rather supported the introduction and scaling up of digital technologies with established evidence. Therefore, this activity was not relevant to the scope of the project. The scheme was on hold as of July 2022, as the application period for the 2022-2023 Adoption Fund closed on July 31, 2022, and there was no information regarding further calls.
England	Digital Health Partnership Award	Digital Health Partnership Award's objective was to accelerate the adoption of new and ready-to-scale digital health technologies by NHS organisations in collaboration with a technology partner and other partners. The award focused on technologies for people with long-term conditions to monitor their health at home or in the community remotely. The program did not provide temporary reimbursement or funding but rather supported the introduction and scaling up of digital technologies in the NHS. Therefore, this activity was not relevant to the scope of the project. The scheme was on hold as of July 2022, as application submission for the third round closed in June 2022, and there was no information regarding further calls.
Estonia	Health system development projects	The Estonian Health Insurance Fund (EHIF) provides grants for projects that present innovative service models, the goals of which are to improve health outcomes and quality of care, improve the treatment pathways, as well as to support the patients requiring care, and to improve prevention methods. The projects are paid from the Innovation Fund of the EHIF. More details on the scheme are presented in the "Initiatives to transform healthcare systems" section. This scheme was considered not relevant for the scope of the project as it consists of various thematic pilot projects; it is not a consistent scheme, eligible for a wide set of medical devices or procedures. Furthermore, the scheme is not annual (applications can be sent and outcomes can be announced at any time, and the projects last for several years).

Country	Framework	Rationale
France	Hospital Program of Clinical Research (PHRC)	PHRC aims to assess the feasibility, efficacy, and safety of innovation methods via government-sponsored research in French hospitals. The program was considered not relevant for the scope of the project as it represents funding for hospital research and does not have a connection to reimbursement (what would be required for coverage with evidence development scheme).
Germany	Early Benefit Assessment (137h Regulation)	The Early Benefit Assessment (according to the 137h SGB V) is not an independent/separate funding program. Early Benefit Assessment is performed in connection with the first-time evaluation of high-risk devices in the NUB program. Details of Early Benefit Assessment are reviewed in connection with the NUB section of the report.
Germany	Selective contracting	The objective of the selective contract framework is to enable greater flexibility and regionality in care. Selective contracts make it possible, for example, to specifically address local peculiarities and to solve special regional and disease-specific healthcare problems. In this way, selective contracts also fulfil an important innovative function: the sickness funds have the opportunity to deviate from collective agreement regulations and establish new healthcare approaches and assess their success. As a result, insured persons from a specific sickness fund have the possibility to benefit from new care approaches, even if not guaranteed by Statutory Healthcare Insurance (SHI). While selective contracts offer temporary coverage, they lack the requirement for evidence generation and connection to national reimbursement. Therefore, this framework was not relevant to the scope of the project.
Germany	Hessen: support for digital innovations	LIDIA is an initiative of the Hessian state government to present funded innovation projects in the digital sector. The platform provides information about new digital technologies and trends in applied research and development. The state of Hessen provides regional funding in multiple programs, which mostly aim at the implementation of digital technologies or at applied research. The supported programs do not qualify for inclusion in the report.
Germany	North Rhine-Westphalia: support for digital innovations	A dedicated portal groups projects and activities in the field of digitalisation of the healthcare system in the state. The state of Nordrhein-Westfalen provides regional funding for projects, which mostly aim at the implementation of digital technologies

Country	Framework	Rationale
		or at applied research. The activities do not qualify for inclusion in the report.
Germany	Saxony: support for digital innovations	The state of Saxony provides regional funding for projects, which mostly aim at the implementation of digital technologies or at applied research. The activities in the state do not qualify for inclusion in the report
Italy	Coverage with evidence development / controlled introduction programs in the Emilia-Romagna region	In 2009-2011 coverage with evidence development was active in the Emilia-Romagna region. Limited information is available about this no longer active program. Transcatheter aortic valve implantation (TAVI) technology was granted access in the region with the responsibility to collect additional evidence. This program is no longer active. As this program did not have at least several entrants (meaning that it was more of a one-off activity) over the course of several years, it was not considered relevant for the scope of the project. Earlier, up to 2009, there was another program focused on the controlled introduction of technologies in the regional health care system with the use of registries to control for the utilisation, covered population, etc. The program was used, at least in the case of radiotherapy for breast cancer and drug-eluting stents. This program is no longer active. As this program did not have at least several entrants (meaning that it was more of a one-off activity) over the course of several years, it was not considered relevant for the scope of the project.
Italy	Coverage with the evidence development program in the Lazio region	Up to 2015, coverage with evidence development activity was practised in the Lazio region. Transcatheter aortic valve implantation (TAVI) technology was granted access in the region after the collection of the evidence via a regional registry. This program is also no longer active. As this program did not have at least several entrants (meaning that it was more of a one-off activity) over the course of several years, it was not considered relevant for the scope of the project.
Luxembourg	Provisional registration of physician services	In Luxembourg, the Medical Expertise Unit (Cellule d'expertise médicale; CEM) may provide recommendations to provisionally (for 1-3 years) register a new physician service in the Nomenclature of Physician Services to the Nomenclature Committee (CN). The CN makes the final recommendations to the Minister of Health and to the Minister of Social Security, which make the final

Country	Framework	Rationale
		decision regarding the registration of the new service and creation of a new code. However, the CEM recommended provisional registration only twice in the last ten years. Furthermore, the Ministers' decision, as well as the Nomenclature, do not provide any details about the provisional registration or its meaning. Therefore, this activity was not relevant to the scope of the project.
Netherlands	Incentive Scheme for E-Health at Home (Stimuleringsregeling E-health Thuis, SET)	The program, administered by ZonMw, provides subsidies for upscaling digital technologies to provide care at home for the elderly and people with chronic illnesses or disabilities. Initially, It had a total budget of €84 million for three years. At the end of 2021, the scheme closed. But due to its success, the Ministry of Health, Welfare and Sport has decided to provide additional funding of €12.5 million for t. Calls for application will be open until December 2022, and the scheme will last until 2025 (assuming no additional budget and new entrants to the scheme). This program was not considered relevant for several reasons listed below. This is a subsidy for the support of a broad range of digital (IT) technologies. Most of the awarded (from 185 granted projects) projects concern very standard (not innovative) IT technologies, including communication platforms, remote consultations, fall sensors, personal alarms, medical dispensing, smart locks, and administration platforms. However, it can also include health apps (e.g., in the field of wound care and mental health). There is no explicit focus on innovative technologies but rather on the general dissemination of digital technologies in home care settings. The program was stopped in 2021, but small additional funding was made available in 2022. The program will have new entrants only until December 2022, and ongoing projects will run until 2025.
Netherlands	Optional service framework / remote monitoring	In the Netherlands, medical procedures within medical specialist care can be reimbursed via DRG or via supplementary payments called "Other care products" (Overige zorgproducten, OZPs). In 2019, a new type of OZP was established by the NZa – the "optional service" (facultatieve prestatie). Optional service is a way for providers and insurers to innovate on the payment model for care, including the creation of new payment categories or replacement of existing payment categories. The "Optional service" model is only applicable to well-established care, which is currently provided as part of Basic Health Insurance.

Country	Framework	Rationale
		Innovations without proven benefits cannot utilise the "optional service" pathway. In October 2021, NZa introduced six new optional services for the telemonitoring of cardiac arrhythmias, hypertension, heart failure, chest pain, COPD, and asthma. This framework is considered a part of the standard financing approach in health care. Therefore, it was not relevant to the scope of the project.
Netherlands	Thematic Technology Transfer (TTT)	This framework does not support the implementation or dissemination of innovations in the health care system. Its aim is to support collaboration and knowledge sharing between research organisations in the Netherlands and to support high-risk investment in medical technologies. Therefore, this framework was not relevant to the scope of the project. This framework is no longer active.
Netherlands	Implementation of knowledge and innovations for appropriate care	The framework provides funding within four different sub-programs aiming at advancing knowledge and implementation of technologies to improve care in the Netherlands. The framework focuses on a wide range of activities, including synthesis, transfer of knowledge (e.g., into the clinical guidelines), and dissemination of technologies. The program does not provide temporary reimbursement or funding but rather supports the introduction and scaling up of technologies in the healthcare system. Therefore, it was not relevant to the scope of the project.
Norway	Support for the introduction of innovative technologies at the regional level	Regional Health Authorities annually allocate some funds for projects aimed at the development or introduction of new and better technologies, organisational methods, and procedures. The following can be used as an example from the Helse Nord in the call for proposals from April 2022: • The project makes use of new ways of working and/or better use of technology; • The project contributes in new ways to reducing unwanted variation in quality and availability in the service offering and improves patient progress; • The project contributes to new and better forms of interaction between companies, municipalities, and/or users of healthcare services;

Country	Framework	Rationale
		• The project is particularly aimed at one or more of the following patient groups: frail elderly people, people with serious mental disorders and substance abuse problems, chronic patients, children, and young people. Examples of previously supported projects at Helse Nord include: • Implementation of digital symptom follow-up of cancer patients (2020); • Artificial intelligence and machine learning in the diagnosis of prostate cancer by PET/MR (2020); • Establishment of robot-assisted PCI (2019). Such activities are established at every Regional Health Authority in Norway. These activities do not qualify for inclusion in the report as they do not represent a temporary reimbursement or funding for medical technologies but are aimed at support of the introduction of a limited number of technologies to regular healthcare services.
Portugal	Early Awareness and alert (EAA) system	INFARMED (an industry association in Portugal) established an Early Awareness and Alert (EAA) system focused on medical technologies several years ago. The objective of the system is to identify and prioritise new or emerging health technologies that have a potential impact on the health system, considering their clinical benefits and associated costs, to support the decision of funders. It is possible to notify INFARMED about relevant technologies via the online form at INFARMED's website. The first and still ongoing call for information relates only to diabetes technologies. This industry-supported system of notifying stakeholders about novel technologies in the diabetes field was not relevant to the scope of the report.
Portugal	Medical Device Reimbursement	Medical Device Reimbursement regulates reimbursement of a limited number of medical aid products (for home use by patients), including devices for self-monitoring of blood glucose, stoma products, and urinary catheters. This program does not fall under the criteria of an innovative payment scheme; it was indeed innovative in the Portuguese settings, but more in the sense of testing a model for reimbursement of products, based on a formal submission, with the potential of some sort of economic

Country	Framework	Rationale
		evaluation. The application form is simplistic. The whole process is very similar to standard processes for medical aids in other EU geographies. The framework does not provide access to a broad range of innovative technologies to the NHS in Portugal.
Scotland	IMTO Process – Scottish Health Technology Group	An IMTO provides a high-level summary of the evidence surrounding health and care innovation in Scotland. It includes a rapid review of evidence to raise awareness about innovations and assist local decision-making. The program does not provide any recommendations. It is an analogue of Medtech Innovation Briefings at NICE. It does not have a connection to actual reimbursement or funding decisions. Therefore, it was not relevant to the scope of the project.
Scotland	Scotland Innovates project / Health Innovation Assessment Portal (HIAP)	The Scotland Innovates service provides an easy-to-use, secure route to connect with the Scottish Public Sector and NHS Scotland. The innovator submits an application to the HIAP; expert assessors evaluate all the information provided in each category: Strategic Fit, Benefits of a Solution, Evidence & Market Readiness, Commercial, and Other Information. The final outcome and relevant feedback are communicated via the portal. Successful applications receive guidance and attention from the NHS and procurement stakeholders in Scotland. This activity does not qualify for inclusion in the report as it does not represent a temporary reimbursement or funding for medical technologies but is aimed at support of the introduction of a limited number of technologies to regular healthcare services.
Sweden	Orderly introduction framework for technologies in Västra Götaland region	The Health Authority of the Västra Götaland region has established a program of orderly introduction of pharmaceuticals and medical technologies in the regional healthcare system. The program only supports technologies with established evidence. Technologies under research are not eligible for this program. Only CE-marked technologies are eligible. The program can be used to support technologies with inequalities in access or underutilisation in the region. To be eligible for inclusion in this framework, the introduction of the technology should lead to additional expenses in the region, or there should be a need for a significant organisational change, or the technology involves a complex ethical problem in access. This activity did not qualify for inclusion in the report as it does not represent a temporary reimbursement or funding for medical

Country	Framework	Rationale
		technologies but is aimed at support of the introduction of a limited number of technologies to regular healthcare services.
Sweden	The activity of the Method and Prioritisation Council in the Skåne region	Method and Prioritisation Council develops health technology assessments to support decision-making about the introduction of novel technologies to the regional healthcare system. The work of the Council represents a classic HTA activity and is not linked to innovation reimbursement or funding activity.
Sweden	Orderly introduction framework for technologies in the Southeastern healthcare region	The southeastern healthcare region consists of three regions (Jönköping, Kalmar, and Östergötland). The healthcare region established a program of orderly introduction of medical technologies in the healthcare system. The process includes an analysis of the application, including evidence analysis of the economic impact, and a decision for the introduction. The outcomes can include an introduction of the method in all three regions, an introduction in a single region, an introduction in the form of the study, and no introduction of the method. This activity does not qualify for inclusion in the report as it does not represent a temporary reimbursement or funding for medical technologies but is aimed at support of the introduction of a limited number of technologies to regular healthcare services.
Sweden	Support for the introduction of innovative technologies at the regional level (regional Innovation Funds)	Regional Health Authorities annually allocate some funds for projects aimed at the development or introduction of new and better technologies, organisational methods, and procedures. Examples of such activities exist almost in every region, including Stockholm and Västra Götaland. These activities do not qualify for inclusion in the report as they do not represent a temporary reimbursement or funding for medical technologies but are aimed at support of the introduction of a limited number of technologies to regular healthcare services.
Wales	Life Sciences Hub Wales	Life Sciences Hub Wales has an objective to catalyze innovation and collaboration between industry, health, social care, and academia in Wales. However, there are no unique funding opportunities or specific coverage with evidence development or innovation funding schemes in place, which are administered by the Hub. Therefore, it was not relevant to the scope of the project.
Wales	Programs of the Bevan Commission	The Bevan Commission is Wales' leading health and care think tank, hosted and supported by Swansea University.

Country	Framework	Rationale
		The Bevan Commission is involved in funding allocation and execution of different research and implementational projects in several programs, including the Planned Care Innovation Programme, Cancer Innovation and Improvement Programme, Adopt and Spread, and Doing Things Differently. These activities do not qualify for inclusion in the report as they do not represent a temporary reimbursement or funding for medical technologies but are aimed at research, analysis, and dissemination of best practices and support of the introduction of a limited number of technologies to the regular healthcare services.

APPENDIX 3 – INACTIVE INNOVATIVE PAYMENT SCHEMES

The main objective of the project was to collect and summarize information about ongoing and emerging innovative payment schemes as of July 01, 2022. However, information about the previously active relevant schemes was also of interest, as some of these schemes laid out a foundation for currently active schemes, and helped to shape the innovation funding landscape in the individual countries.

For these reasons, inactive innovative payment schemes are listed and reviewed in Appendix 3. There was no aim to create an exhaustive list of inactive schemes, as these were out of the scope of the project.

England: Commissioning Through Evaluation [INACTIVE]

Title

Commissioning Through Evaluation.

Objective

NHS England's Commissioning through Evaluation (CtE) program enabled a limited number of patients to access treatments that are not funded by the NHS but, nonetheless, show significant promise for the future while new clinical and patient experience data are collected within a formal evaluation program. CtE represented a coverage with evidence development program.

NB! The scheme was discontinued in 2021.

The CtE scheme was discontinued as it was merged into the Evaluative Commissioning program. The program includes the following: communicating with research funders over priorities for further research in specialized care following advice from national expert clinicians; managing the assurance of excess treatment costs for trials in receipt of research grant funding from the National Institute for Health and Care Research (NIHR) or the Association of Medical Research Charities (AMRC) members; direct involvement in some "public value" trials; the collaborative development of trials in more challenging research areas through the National Research Collaboration Programme with NIHR.

The information on the Evaluative Commissioning (EC) program is available in Specialised Commissioning: Service development policy and methods. The EC scheme enables a limited number of patients to access treatments for which NHS England already has a "not for routine commissioning" policy, but which shows significant promise for the future, based on new clinical and patient experience data collected about the use of the treatment within a formal evaluation program. The data collected from an EC scheme can then be considered alongside published data from research trials by the Clinical Panel as part of the evidence review. No further information regarding the Evaluative Commissioning program is available.

Overview

Commissioning through Evaluation, launched in 2013, was an integral part of the national commissioning process by NHS England. It did not concern procedures commissioned locally by the Clinical Commissioning Groups.

In the process of the review of procedures for routine commissioning, NHS England could conclude that a procedure was promising but that the evidence was not yet sufficient to routinely commission the procedure. When NHS England saw the potential to bridge the evidence gap to inform a commissioning decision, the procedure could be selected to enter into the CtE program.

So, enrolment into the program started with a review of the procedure/technology by NHS England and a decision not to commission it routinely. The relevant Clinical Reference Group at NHS England suggested a topic for CtE. The topic was reviewed by the Board of the National Program of Care and directed to the Specialised Services Clinical Panel. The Panel, jointly with the National Institute for Health and Care Excellence (NICE), developed the formal proposal for the study. At the end of the topic selection phase, the study was confirmed.

The next phase of the process was the recruitment phase, with the selection of hospitals and the recruitment of patients. Only a limited number of hospitals were included. The number of patients in the scheme was also limited.

After the completion of the study, an External Assessment Centre commissioned by NICE performed an analysis of the study data and, in parallel, performed an evidence review for the procedure. The Center and NICE jointly published the final report of the program. NHS England performed a repeat review of the technology and considered it for routine commissioning nationally.

NHS England fully sponsored the studies. They typically had case series / before and after a design that was organized in the form of registries. The sample size of the study could be up to 400 patients.

The study typically lasted for about three years. The following is an example of the timelines for selective radioembolization: selection for the program in 2013; a study conducted between December 2013 and March 2017 (3 years and three months); a final report from NICE and External Assessment Center was issued in July 2017.

Care settings

In-patient settings.

Type of covered technologies

Medical devices, medical procedures.

Inclusion criteria

NHS England released the following inclusion criteria:

- The topic fell within NHS England's direct commissioning responsibilities for specialized services;
- The treatment or care pathway showed significant promise as a potential, future, routine NHS treatment approach;
- A policy had been published confirming that the treatment was not routinely commissioned (NRC) or that the topic represents an area of specialized care where there were significant remaining questions regarding clinical or cost-effectiveness and/or outcomes in the routine clinical setting;

- Key questions of clinical and/or cost-effectiveness remain that would not be answered by current or planned clinical trials;
- Meaningful new outcome data could be gathered within the likely timescale of a CtE (typically 1-2 years).

Applicant

It was not possible to apply for inclusion in the scheme. The NHS England activated it in the process of review of the procedure for national commissioning. Inclusion in the scheme was an outcome of the negative assessment of technology for national coverage by NHS England.

Stakeholders involved

Stakeholder	Role
Clinical Reference Groups at NHS England	Suggestions for topic selection
Board of National Programs of Care at NHS England	Review of the suggested topics
Specialized Services Clinical Panel at NHS England	Selection of the technology Jointly with NICE: development of the proposal for the study
National Institute for Health and Care Excellence (NICE)	Jointly with Specialised Services Clinical Panel at NHS England: development of the proposal for the study Commissioning of the analysis of the study to the External Assessment Center Review of the overall findings of the study and external evidence review and production of the final report of the program
External Assessment Center	Performs analysis of study results Performs evidence review

Role of the industry

The industry had no direct role in this scheme.

Clinical and economic requirements for the scheme

There were no defined requirements for the scheme. The procedure had to be first negatively evaluated by NHS England for routine national commissioning. The procedure had to have good but not yet sufficient evidence to justify routine commissioning by NHS England. It had to be possible to bridge the knowledge gap with the study (typically, using registry format).

Statistics and trends about the use of the scheme

A total of six technologies were evaluated within the scheme between 2016 and 2021 (link).

Technology	Status of the study/evaluation	Impact on commissioning policy
Selective Dorsal Rhizotomy (SDR) to increase mobility in children with cerebral palsy	The study was completed in 2016, and the evaluation report was published in 2018	Clinical Commissioning Policy was updated in 2019. The procedure is routinely commissioned
Selective Internal Radiation Therapy (SIRT) for liver cancer	The evaluation report was published in 2017	Clinical Commissioning Policy for chemotherapy-refractory intolerant metastatic colorectal cancer was released in 2018; the procedure is routinely commissioned Clinical Commissioning Policy for chemotherapy-refractory or intolerant, unresectable primary intrahepatic cholangiocarcinoma was released in 2019; the procedure is not routinely commissioned
Percutaneous Mitral Valve Leaflet Repair (Mitraclip) for mitral regurgitation	The evaluation report was published in 2019	Clinical Commissioning Policy was released in 2019. The procedure is routinely commissioned
Patent Foramen Ovale (PFO) Closure to prevent recurrent stroke	The evaluation report was published in 2018	Clinical Commissioning Policy was released in 2019. The procedure is routinely commissioned
Left Atrial Appendage Occlusion (LAAO) to prevent stroke	The evaluation report was published in 2019	Clinical Commissioning Policy was released in 2019. The procedure is routinely commissioned
Stereotactic ablative radiotherapy (SABR) for patients with previously irradiated, locally recurrent para-aortic or primary pelvic tumours (All ages)	The evaluation report was published in 2021	Clinical Commissioning Policy for patients with para-aortic tumours was released in 2021; the procedure is not routinely commissioned Clinical Commissioning Policy for patients with primary pelvic tumours was released in 2021; the procedure is routinely commissioned

Bionic Eye Surgery was considered for the beginning of the Commissioning through Evaluation program, but the evaluation has never started.

Reference

No particular web-link to the scheme exists.

England: Innovation and Technology Tariff [INACTIVE]

Title

Innovation and Technology Tariff.

Objective

The Innovation and Technology Tariff (ITT) was introduced to incentivise the adoption and spread of transformational innovation in the NHS. The scheme was classified as an innovation funding scheme.

NB! The scheme was stopped in 2018 and completely replaced by the Innovation and Technology Payment scheme.

Overview

The scope of the program was on already established technologies from which NHS can benefit. Proposed technologies should meet the requirements/criteria for the call for applications (see below). Selection, in general, was made in connection with the NHS Innovation Accelerator (NIA) program (support of individual research fellows).

The selection process in 2016, the first year of the program, was administered via the NHS Innovation Accelerator's website by NHS England. However, the responsible entity for the program was then changed to the Innovation and Research Unit at NHS England. NHS England made the ultimate selection and funding decision.

For selected technologies, reimbursement with national tariff was granted for a 2-year period and funded by NHS England (irrespective of the responsible commissioner for the procedure). Most of the procedures were reimbursed via a so-called "zero cost model". In this model, providers ordered the innovations from the supplier at no cost, and NHS England reimbursed the supplier directly. The cost of the implementation of innovation was not covered.

The inclusion of novel technologies in the program was discontinued in 2018, and the scheme was completely replaced by Innovation and Technology Payment.

Care settings

In-patient, out-patient specialist settings, and community care. Decisions mostly concerned hospital and out-patient specialist settings, except for myCOPD (health app), which is used by the patient at home.

Type of covered technologies

Medical devices, in-vitro diagnostic tests, diagnostic technologies, and digital health technologies.

Inclusion criteria

In the first application round in 2016, the following topics were considered:

- Mature innovations with a validated evidence base, already in use and ready for scaling;
- An innovation that delivers significantly increased quality and improved efficiency;
- Must be utilised in a service that is reimbursed through the national tariff; for example, acute inpatient services, hospital out-patients, or A&E;
- The innovation will need to have a suitable pricing structure, e.g., price per patient, either as part of an episode of care or as an attendance.

Exclusion criteria in 2016 were:

- Primary care services (general practice, community pharmacy, dental practice, and community optometry), for example, are substantively not covered by the national tariff and, therefore, are excluded from the innovation and technology tariff;
- Innovations already widely used across the NHS;
- Innovation that involved capital investment or set-up costs and was unlikely to be applicable for a national tariff.

Applicant

While the scheme was active, the manufacturer (developer of the technology) could make an application.

Stakeholders involved

Stakeholder	Role
NHS Innovation Accelerator	Call for an application, collection of proposals
NHS England	Review of the proposals, overview supervision of the scheme, ultimate funding decision Funding of the method within the 2-year period
System partners (including Arm's Length Bodies, Clinicians)	Input into the decision-making process
Academic Health Science Networks (AHSNs)	Support for the implementation of innovation

Role of the industry

Manufacturers could make applications for the scheme.

Clinical and economic requirements for the scheme

One of the main requirements of the program was that the technology should be established, although no specifics were provided.

In the public consultation in relation to the initiation of the scheme, NHS England and NHS Improvement received feedback that the ITT should be connected to NICE medical technology reviews. However, no formal connection has been established.

Statistics and trends about the use of the scheme

Six technologies were selected for funding in the 2017/18 and 2018/19 financial years. Five technologies received a national, unbundled tariff that was paid on top of the HRG by NHS England, irrespective of the commissioning status. For the sixth technology - management of Benign prostatic hyperplasia as a day case using Urolift – the costs were covered by already existing HRGs in the National Tariff Payment System, so no separate tariff was introduced.

The specifics of the payment are provided in the table below (extract from the National Tariff Payment System for 2017/19) (link).

ITT Code	ITT Theme	ITT product specification	Payment mechanism
ITT-01	Guided mediolateral episiotomy to minimize the risk of obstetric anal sphincter injury	Alternative to the standard episiotomy scissors to facilitate accurate mediolateral episiotomy during labour at 60 degrees to the perineal midline	On top of HRG, per use of Episcissors
ITT-02	Arterial connecting systems to reduce bacterial contamination and the accidental administration of medication	Needle-free arterial non-injectable connector (NIC) devices	On top of HRG, per device
ITT-03	Pneumonia prevention systems that are designed to stop ventilator-associated pneumonia	PneuX system	On top of HRG, per device
ITT-04	Web-based applications for the self-management of chronic obstructive pulmonary disease	MyCOPD	On top of HRG, per patient registration
ITT-05	Frozen faecal microbiota transplantation (FMT) for recurrent Clostridium difficile infection rates	Providers should follow the NHS West Hampshire CCG Community Management of Clostridium difficile Infection Pathway	On top of HRG, per patient use
ITT-06	Management of Benign prostatic hyperplasia as a day case	Urolift	Included into HRG (LB70C, LB70D)

In parallel, but separately from the ITT, NHS England centrally funded the seventh theme, "Identification and measurement of atrial fibrillation through mobile ECG technology".

Reference

No particular web-link to the scheme exists.

England: Innovation and Technology Payment [INACTIVE]

Title

Innovation and Technology Payment (ITP).

Objective

The Innovation and Technology Payment (ITP) aimed to support the NHS in adopting innovation by removing financial or procurement barriers to the uptake of innovative products or technologies. This program was launched in 2017, and the first funding started in April 2018.

NB! The ITP program was discontinued on April 01, 2021, and partially replaced by the MedTech Funding Mandate.

Overview

The ITP was looking to support medical devices, digital platforms, and technologies. The program was not suitable for pharmaceutical products or research projects. The ITP was explicitly focused on low-cost innovations that could deliver significant patient outcomes and cost savings to NHS.

NHS England identified technologies via a competitive process and determining ways to support these innovations, either via reimbursement for usage or by the central procurement of the technologies.

The program represented the key mechanism to fund low-cost innovations at NHS, which had financial barriers to accessing the UK market. The program was connected to the work of the Accelerated Access Collaborative (AAC).

The program was launched in 2017, with the first funding starting in April 2018. The funding could be available for a period of one year, after which the program and funded themes were reviewed. Day-to-day support and coordination of the program were performed by NHS England's Innovation, Research, and Life Sciences Unit. Total spending for the 2018/19 and 2019/20 programs was around £17 mln. Innovations that did not have enough evidence to receive ITP could be supported via Digital Evidence Generation (EGF).

The application process was the following: Call for proposals launched in June-September. Applications were received from July until September-October. Two application-sifting rounds took place in October and November. A decision panel selected the final cohort for further due diligence and commercial discussions in December. The scheme was launched in April (the start of the financial year in England).

The ITP program was discontinued in April 2021. As the program's aim was the broader adoption of cost-saving technologies, most of the technologies were included in routine commissioning and procurement processes after its completion. Some ITP products continue to be supported by the MedTech Funding Mandate.

Care settings

In-patient, out-patient specialist settings.

Type of covered technologies

Medical devices, in-vitro diagnostic tests, diagnostic technologies, and digital health technologies.

Inclusion criteria

The following inclusion criteria were applicable (for the first call for proposal for 2018/19 funding):

- Had a demonstrated (in practice – not theoretically or hypothetically) benefit to the NHS through increasing quality, health, and well-being and creating efficiency;
- Were at the correct phase of innovation – as such, applicants were required to show that their innovation was supported by a robust evidence base and was ready to be diffused widely across the NHS;
- Could demonstrate that a return on investment could be achieved by the NHS within a timeframe of a year if the innovation was more widely taken up and diffused in the NHS;
- Faced financial or procurement barriers to wider adoption and diffusion in the NHS that could be overcome with central financial support;
- Low cost. This program was targeted at innovations that could be diffused quickly and at a low cost;
- Had satisfied all necessary regulatory, intellectual property, and ethical frameworks within the applicant's host country.

For 2019/20, more simplified criteria were used:

- NICE support (through a Medtech Innovation Briefing or Guidance);
- Positive in-year return on investment;
- Use in at least three NHS organisations.

For 2020/21, the following criteria were applied to the products that have been previously supported through the ITT/ITP program:

- Not received a negative NICE appraisal;
- Proven to deliver clinical benefits and are cost-effective;
- Not already supported by the National Tariff Payment System.

Priority areas were determined in Next Steps in the Five Year Forward View and NHS Business Plan.

Applicant

While the scheme was active, applicants could have been from any of the following: healthcare, academic, and commercial or voluntary sectors.

Stakeholders involved

The following stakeholders were involved:

Stakeholder	Role
NHS England's Innovation, Research, and Life Sciences Unit	The key operator of the framework
NHS England	Determination of the funding scheme, funding of the technology
System partners	Involved in the design and development of the scheme; involved in assessing the relevant innovations and their suitability for the program
Decision-making panel	Decision-making about the selection of the technologies (co-chaired by representatives of the NHS England and AHSN)
Academic Health Science Networks (AHSNs)	Implementation of the scheme, participation in sifting, and decision-making about the selection of the technologies

The decision-making panel was established to review all applications that reached the final stage and consider the resulting scores and recommendations. The panel was co-chaired by Ian Dodge, NHS England's National Director of Strategy and Innovation, Tara Donnelly, Chief Officer of the Health Innovation Network (South London AHSN), and Professor Steve Feast, Chief Officer of Eastern AHSN. It included relevant National Clinical Directors, Arm's Length bodies (such as NICE), and representatives from industry and patient groups.

Role of the industry

Manufacturers could make applications for the scheme.

Clinical and economic requirements for the scheme

Accompanying documents for the scheme specify that applications had to include robust evidence to demonstrate that their innovation had a genuinely high impact, was affordable, and was at the correct level of maturity and relevance for widespread diffusion. However, details were not available.

Applicants had to describe efforts that had been made to widen the adoption of their innovation in the NHS and the barriers that they and NHS organisations had encountered.

The key requirement was that the return on investment within one year had to be demonstrated.

Seven technologies supported by the ITP were evaluated at NICE:

- HeartFlow – was evaluated in NICE Medical Technology Guidance (MTG32), published in February 2017;
- EndoCuff Vision - was evaluated in NICE Medical Technology Guidance (MTG45), published in June 2019 (after being supported with ITP);

- SecurAcath - was evaluated in NICE Medical Technology Guidance (MTG34), published in June 2017;
- gammaCore – was reviewed in NICE Medical Innovation Briefing (MIB162), published in October 2018; and in NICE Medical Technology Guidance (MTG46), published in 2019 (after being supported with ITP);
- SpaceOAR hydrogel – NICE Medical Technology Guidance was in development (GID-MT526);
- Elecsys immunoassay sFlt-1/PlGF ratio – was evaluated in NICE Diagnostic Guidance (DG23), published in May 2016;
- Elecsys Troponin T high-sensitive – was evaluated in NICE Diagnostic Guidance (DG15), published in October 2014.

Statistics and trends about the use of the scheme

In April 2018, the first round of financing starting the 2018/19 financial year included the following technologies (funding continued after the first year):

- HeartFlow – advanced image analysis software that creates a 3D model of the coronary arteries and analyses the impact that blockages have on blood flow to rapidly diagnose patients with suspected coronary artery disease. The use of the device can avoid the need for invasive investigations such as coronary angiography, usually carried out under local anaesthetic, where a catheter is passed through the blood vessels to the heart to release a dye before X-rays are taken. NICE estimates that up to 35,000 people per year could be eligible;
- Plus Sutures – A new type of surgical suture – stitching – that reduces the rate of surgery-linked infection (surgical site infection), such as MRSA, through the use of antimicrobial suture packs. There were 823 cases of MRSA reported in the NHS in 2016/17;
- Endocuff Vision – A new type of 'bowel scope' that improves colorectal examination for patients undergoing bowel cancer tests. Bowel cancer is the fourth most common cancer in England, with 34,000 people diagnosed each year. For every 1,000 people screened for cancer, it is estimated that six cases could be avoided thanks to early detection through the use of this device;
- SecurAcath – A device to secure catheters that reduces the infection risk for patients with a peripherally inserted central catheter. The use of this equipment helps to reduce the time taken to care for and treat dressing changes. This type of catheter is normally used in people needing intravenous access for several weeks or months in both inpatient and outpatient settings. NICE estimates that up to 120,000 people per year could be eligible.

In the 2019/20 financial year, a total of 142 innovations were submitted, and four technologies were selected for funding (3% success rate):

- gammaCore, a non-invasive vagus nerve stimulation therapy for the treatment of cluster headaches;
- SpaceOAR, an absorbable spacer to reduce rectum radiation exposure during prostate radiation therapy;
- Placental growth factor (PlGF) based test for the rule-out of pre-eclampsia;

- High sensitivity troponin assay in a rapid rule-out protocol for acute myocardial infarction.

Additionally, two technologies were supported via Evidence Generation Fund:

- Digital apps to support emergency/crisis mental health assessments;
- Interoperable personal health record tool.

In the 2020/21 financial year, the ITP program supported eight innovations (until March 31, 2021) (link):

- Placental growth factor (PlGF) based testing;
- HeartFlow FFRCT;
- gammaCore;
- SpaceOAR;
- Non-Injectable Connector;
- Plus Sutures;
- SecurAcath;
- Endocuff Vision.

As of July 01, 2022, four ITP products (PlGF-based testing, SecurAcath, HeartFlow FFRCT, and gammaCore) continue to be supported through MedTech Funding Mandate.

Reference

Web-link to the scheme.

France: ETAPES program [INACTIVE]

Title

Experiments in Telemedicine for the Improvement of Health Pathways (Expérimentation de Télémédecine pour l'Amélioration des Parcours en Santé, ETAPES).

Objective

The objective of the ETAPES program was to create an experimental approach to encourage innovative initiatives and to support telemonitoring at the national level. The program covered remote medical monitoring (medical surveillance and devices for telemonitoring) in five disease areas: chronic heart failure, chronic kidney failure, chronic respiratory failure, diabetes, and implantable cardiac devices.

NB! The ETAPES program was formally discontinued on August 01, 2022 and was replaced by the regular reimbursement framework for remote medical monitoring. However, the reimbursement for remote monitoring via the ETAPES program will be maintained until the reimbursement conditions and tariffs for remote monitoring under the new framework are established (maximum until December 31, 2022).

Since July 1, 2022, remote medical monitoring has been covered by statutory health insurance via the new reimbursement framework (according to Article 36 of the Social Security Financing Act for 2022). The new framework includes the development of a specific list called "Telemonitoring List" ("Liste Télésurveillance") with tariffs and reimbursement conditions for remote medical monitoring (medical surveillance services and digital medical devices); however, it has not been published as of September 15, 2022.

Remote monitoring medical devices registered in the LPPR List will be removed from this list no later than January 1, 2023.

Overview

In 2014 the telemedicine experiments, including teleconsultation, tele-expertise, and telemonitoring, were initiated under the national program "Experiments in Telemedicine for the Improvement of Health Pathways" (Expérimentation de Télémédecine pour l'Amélioration des Parcours en Santé, ETAPES). Since 2018, teleconsultation and tele-expertise have been covered by statutory health insurance (Article 54 of the Law on Social Security Financing for 2018). The telemonitoring experiments for five disease categories continued under the ETAPES program from January 1, 2018, until August 1, 2022.

Funding for remote medical monitoring within the ETAPES program included three components:

- Payment for the physician performing telemonitoring (TSM);
- Payment to the health professional providing the therapeutic support to the patient who is being monitored remotely (TSA);

- Payment to the provider of a technical solution for telemonitoring (FSF), including a connected medical device, health app, digital platform, or a combination of all the above mentioned.

The reimbursement amount for each ETAPES sub-program is provided in the table below. In relation to the telemonitoring solution, the provider of the solution was paid a fixed amount between €225 and €375 per semester (depending on the clinical area). The payment was not provided for telemonitoring solutions connected to implantable cardiac devices, as the cost of telemonitoring was already considered in their reimbursable LPPR tariff.

Categories of patients		The physician performing the telemonitoring (TSM)	Health professional providing therapeutic support to the patient who is being monitored remotely (TSA)	Provider of remote monitoring solution (TSF)
		Fixed lump-sum payment per semester (half-year period) (€) (for year N)		
Chronic heart failure patients		110	60	300
Chronic kidney failure patients	a) Patients with chronic renal failure on dialysis	73	30	300
	b) Kidney transplant patients	36.50	30	225
Chronic respiratory failure patients		73	30	300
Diabetes patients	a) Type 1 & 2 diabetes with complex insulin regimens	110	60	375
	b) Type 2 diabetes with single insulin injection	110	60	300
Implantable cardiac devices		65	-	LPPR List tariff

The solution provider invoiced the health insurance every two months for a third of the semestral (half-year period) amount. At the end of the semester, the responsible physician would check whether the patient was still eligible for telemonitoring. If so, the patient would be prescribed telemonitoring services again and is still part of the ETAPES program.

The service provider could have also received a bonus. Any potential yearly (N) bonuses were paid in the following year (N+1). The bonuses for the solution providers were equal to 30% of the difference in costs achieved compared to the previous year (Bonuses = 30% * [(Total Costs Year N-

1) – (Total Costs Year N)]), adjusted to the number of patients who benefit to this supplier's solution. The requirements to achieve the bonus included:

- Chronic heart failure:
  - Requirements: Heart failure-related hospitalisation was reduced by more than 20% compared to the previous year (N-1);
  - Limit per year per patient: €300;
- Kidney failure (a):
  - Requirements: A reduction in RCL (decline in utilisation of fully staffed dialysis centres) of more than 10%, or total health costs reduction of more than 5%, compared to the previous year (N-1);
  - Limit per year per patient: €300;
- Kidney failure (b):
  - Requirements: A reduction in graft rejection of more than 10% of total health costs reduction or more than 5% compared to the previous year (N-1);
  - Limit per year per patient: €225;
- Chronic respiratory failure:
  - Requirements: All-cause hospitalisation reduced by more than 10%, or total health costs reduced by more than 10%, compared to the previous year (N-1);
  - Limit per year per patient: €300;
- Diabetes (a & b):
  - Requirements: All-cause hospitalisation reduced by more than 15%, or total health costs reduced by more than 16%, compared to the previous year (N-1);
  - Limit per year per patient: €330;
- Implantable cardiac prostheses:
  - No bonuses available.

Care settings

Out-patient specialist settings, community (medico-social) facilities, and home care. The program was not applicable to hospitalised patients.

Type of covered technologies

Digital medical devices for remote monitoring.

Inclusion criteria

The criteria for reimbursement of a medical device via the ETAPES program were the following:

- The device (technical solution) was supposed to be compliant with the regulatory framework for remote monitoring in one of five disease areas considered in the ETAPES programs;
- The device was supposed to be CE marked; in addition, technical solutions that qualified as medical devices must have complied with a CE marking regulatory approval procedure of at least class IIa (in accordance with European regulation 2017/745 of May 26, 2020);

- The device should have complied with the interoperability and safety standards of the Digital Health Agency (l'Agence du numérique en santé, ANS).

More details on the conditions for the implementation of remote monitoring experiments, including specific requirements for patients eligible for telemonitoring services, were defined by specifications that were published by the Ministry of Health in October 2018.

Applicant

The manufacturer of the medical device for remote monitoring, the authorised representative of the manufacturer, or a distributor of the device could submit the applications.

Stakeholders involved

Stakeholder	Role
Ministry of Health and Prevention	Development of the ETAPES program framework Establishment of reimbursement tariffs Approval of technical solutions (including medical devices) for the ETAPES program
Regional health agencies (Agences régionales de santé, ARS)	Funding of experiments under ETAPES program
National Authority for Health (HAS)	Medico-economic, social, qualitative, and quantitative evaluation of results of experiments under the ETAPES program

Role of the industry

The manufacturers of the medical device for remote monitoring could submit applications for inclusion in the ETAPES program (only for established categories).

Clinical and economic requirements for the scheme

For obtaining reimbursement via the ETAPES program, the medical device should have had a remote monitoring function for one of the five defined disease areas (chronic heart failure, chronic kidney failure, chronic respiratory failure, diabetes, and monitoring for implantable cardiac devices). The medical devices must have also fulfilled the abovementioned inclusion criteria.

There were no specific economic requirements that the medical devices for remote monitoring must meet to receive financial support via the ETAPES program.

Statistics and trends about the use of the scheme

As of July 1, 2022, a total of 121 technical solutions for remote monitoring were approved for reimbursement via the ETAPES program.

Data about the number of technical solutions for remote monitoring reimbursed via the ETAPES program is presented in the table below (link). The technical solutions for remote monitoring of implantable cardiac devices are not included in the list if they were covered by the LPPR tariff for the device.

	2017	2018	2019	2020	2021	2022 (until July 1)
Number of approved technical solutions for the remote monitoring	9	48	24	12	20	8

Some examples of solutions that were covered by the ETAPES program are listed in the table below:

Solution	Manufacturer	Indication for remote monitoring	Date of implementation
Diabéo	Sanofi Aventis	Diabetes	October 18, 2017
Covotem	GCS Normand'e-santé	Chronic heart failure	October 31, 2017
Insulia	Voluntis	Diabetes	November 13, 2017
One minute for my heart	Newcard	Chronic heart failure	November 27, 2017
Home Monitoring	Biotronik	Implantable cardiac devices	December 05, 2017
NOMHADChronic	CDM e-Health	Chronic respiratory failure Chronic heart failure Diabetes	December 05, 2017
Latitude NXT	Boston Scientific	Chronic heart failure Implantable cardiac devices	December 12, 2017
Merlin.net	Abbott Medical France	Implantable cardiac devices	December 18, 2017
MyDiabby Healthcare	MDHC	Diabetes	December 22, 2017
Engage V7	Exolis	Chronic respiratory failure Chronic heart failure Chronic kidney failure Diabetes	February 03, 2022

Solution	Manufacturer	Indication for remote monitoring	Date of implementation
My-promantis	Promantis	Chronic heart failure	March 04, 2022
Diabnext	Glooko SAS	Diabetes	April 26, 2022
Apilife Medical	Cibiltech	Chronic respiratory failure	April 26, 2022
Apilife Medical	Cibiltech	Chronic heart failure	May 31, 2022
UNIFORMS module of the UNIQ solution	Move in Med	Chronic respiratory failure Chronic heart failure Chronic kidney failure Diabetes	May 31, 2022
eNephro	Equasens	Chronic kidney failure	June 01, 2022
PHEAL	PHEAL	Chronic respiratory failure	June 28, 2022

As of September 30, 2019, 32,600 patients were involved in the ETAPES program (reference).

Reference

Web-link to the scheme.

The Netherlands: Conditional funding of medical procedures [INACTIVE]

Title

Conditional funding of medical technologies within Basic Health Insurance (Voorwaardelijke toelating tot het basispakket).

Objective

The scheme's objective was to provide temporary reimbursement and funding for innovative procedures for which evidence is insufficient to grant permanent coverage within Basic Health Insurance. The scheme is classified as coverage with evidence development program.

NB! Since January 1, 2019, it is no longer possible to submit new applications for this conditional funding scheme, as it was replaced by the "subsidy scheme for promising care". However, some projects are still funded via this scheme.

Overview

Basic Health Insurance is determined/guaranteed in the Netherlands by the Health Insurance Law (Zorgverzekeringswet, Zvw). The Law describes care in general terms, so there is a lack of clarity in many situations regarding what is covered. Dutch Health Care Institute (Zorginstituut Nederland) determines care allocation under Basic Health Insurance. The position of the Dutch Health Care Institute is based on an assessment of clinical and economic evidence to determine the compliance of care with "state of science and practice" criteria. Care is reviewed according to the requirements of necessity, effectiveness (conformity with the "state of science and practice"), cost-effectiveness, and feasibility (later – only in case of review before the implementation of the method).

There are three ways to initiation of the Dutch Health Care Institute assessment of technology:

- Dutch Health Care Institute receives questions from health insurers, health care providers, and patients on whether care should be covered within Basic Health Insurance. Institute responds to the requesting party with an answer and interpretation (relatively rare way);
- Dutch Healthcare Authority (NZa) can request assessment during the process of the evaluation of the need for the creation of the procedure code (meaningful way);
- In addition to responding to requests from different stakeholders, the Dutch Health Care Institute regularly reviews the care package (important way).

When the Dutch Healthcare Institute does not confirm compliance with the "state of science and practice", the procedure is declined coverage within Basic Health Insurance. If care does not meet the criteria of "state of science and practice" but is promising. In that case, the Institute could open the possibility of temporary, conditional funding for up to four years. If sufficient evidence data has not been obtained within four years, the Dutch Health Care Institute can recommend extending the project's duration.

The conditional funding of medical technologies was established in January 2012. The pre-condition for submission was the assessment from the Dutch Health Care Institute, which did not find the evidence sufficient to recommend technology for reimbursement within the basic health insurance package but mentioned the possibility of conditional reimbursement.

Applications for temporary reimbursement should be made within three months after the release of the recommendation of the Dutch Health Care Institute about coverage of procedures within Basic Health Insurance.

Application triggered the complex 4-stage process of the selection of candidate technologies. The condition for temporary reimbursement included a collection of data about effectiveness and cost-effectiveness. During the reimbursement period, a clinical trial should be conducted in the Netherlands to bridge evidence gaps. The Dutch Health Care Institute releases annual progress reports about technologies for which temporary reimbursement was provided.

Since conditional reimbursement has been activated, the cost of care is covered by Basic Health Insurance. The basic health insurance spendings on conditionally admitted methods were €7.3 million in 2021. However, the cost of research itself shall be covered by private parties (e.g., the manufacturer). After the completion of the research period, the Dutch Health Care Institute reevaluates the service in scope and makes final recommendations about its inclusion in the Basic Health Insurance package. The final decision on the inclusion of technology in the Basic Health Insurance package is made by the Ministry of Health, Welfare and Sport.

Care settings

In-patient, out-patient specialist settings.

Type of covered technologies

Medical devices and medical procedures, pharmaceuticals.

Inclusion criteria

Selection criteria for services included the appropriateness of the intervention, the research feasibility, social relevance, and the promise of the service.

Applicant

There was no application for the program. The applicant (manufacturer) could be offered participation in the conditional reimbursement scheme after a negative coverage decision by the Dutch Health Care Institute.

Stakeholders involved

Stakeholder	Role
Dutch Health Care Institute (Zorginstituut Nederland)	Informs manufacturers about the possibility of applying for temporary reimbursement Collects and reviews applications Advices Ministry of Health, Welfare and Sport and potential candidates for reimbursement Makes reevaluation of the procedure after the end of the conditional period
Scientific Advisory Council (WAR)	Advice about the selection of applicants
Dutch Organisation for Health Research and Development (ZonMw)	Hosts system for submission of dossiers Provides advice to the ZIN about the quality of feasibility of the research Provides subsidy for the financing of the research component
Ministry of Health, Welfare, and Sport	The decision about awarding conditional reimbursement The decision about inclusion in the Basic Health Insurance package

Role of the industry

Manufacturers of medical devices, together with research institutions and healthcare providers, can apply for conditional funding after a negative coverage decision by the Dutch Health Care Institute.

Clinical and economic requirements for the scheme

Technology should be promising and have a certain amount of evidence, which is nevertheless insufficient for permanent coverage within Basic Health Insurance. A clinical study in the Netherlands should be sufficient to bridge the evidence gap to inform a definitive decision about coverage within Basic Health Insurance.

Statistics and trends about the use of the scheme

Data about the total number of selected projects and projects related to medical technologies (including cell therapy) for five-year (2014-2018) are presented below.

Status	2014	2015	2016	2017	2018
Total number of selected projects (drugs and devices)	5	8	7	3	5
Number of selected projects related to medical technologies (%)	3 (60%)	6 (75%)	5 (71%)	2 (67%)	3 (60%)

As of July 1, 2022, there are 11 ongoing projects under the conditional funding scheme (link):

- Long-term active physiotherapy in patients with axial spondyloarthritis with severe functional impairment (extended until July 1, 2024);
- Long-term active physiotherapy in patients with rheumatoid arthritis with severe functional impairment (extended until July 1, 2024);
- Nusinersen (Spinraza®) in patients with 5q spinal muscular atrophy (SMA) who are 9.5 years and older (until December 31, 2026);
- Bladder instillation with bladder irrigation fluids in patients with bladder pain syndrome and Hunnerse lesions (extended until July 31, 2025);
- CardioMEMS Pulmonary Artery Monitoring in patients with chronic heart failure New York Heart Association Class III with recurrent hospitalisations (until March 1, 2024);
- Treatment with tumour-infiltrating lymphocytes (TIL) in metastatic melanoma irresectable stage IIIc and stage IV (extended until January 1, 2023);
- Breast reconstruction after breast cancer with autologous fat grafting (AFT) (until September 30, 2020);
- Combination treatment of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (HIPEC) in patients with gastric carcinoma as well as synchronous peritoneal metastases or tumour-positive peritoneal fluid (until December 31, 2026);
- Hyperthermic intraperitoneal chemotherapy (HIPEC) added to primary debulking in patients with stage III ovarian cancer (until December 31, 2026);
- Intensified alkylating chemotherapy with autologous stem cell transplantation for the treatment of stage III BRCA1-like breast cancer (extended until January 1, 2025);
- Medical silver clothing and antibacterial dressings with chitosan addition in children and adults with moderate to severe atopic eczema (extended until January 1, 2024).

The information on the progress for 2021 related to selected projects can be found in the 2022 progress report.

Reference

Web-link to the scheme.