Med Tech
Reimbursement
Consulting

INNOVATIVE PAYMENT SCHEMES FOR MEDICAL TECHNOLOGIES AND IN-VITRO DIAGNOSTIC TESTS IN EUROPE

MTRC Research Paper
June 2018

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EXECUTIVE SUMMARY

European Med Tech and IVD Reimbursement Consulting Ltd. used its in-house expertise to identify and provide an overview of the innovative payment schemes for medical devices and in-vitro diagnostic tests in European countries. The availability of innovative payment schemes was studied in Austria, Belgium, Denmark, England, Finland, France, Germany, Italy, the Netherlands, Norway, Spain, Sweden and Switzerland.

Two types of schemes were considered: coverage with evidence development (funding with requirement to perform a clinical study to bridge the evidence gaps) and innovation funding (funding with no requirements to perform a study).

Out of 13 studied countries, 7 countries (Austria, Belgium, England, France, Germany, the Netherlands and Switzerland; 54%) had innovative payment schemes in place. On average, there were 2 innovative payment schemes per country. The largest number was available in France (n=4) and England (n=3); Austria, Belgium and Switzerland each had one program in place.

In total, 14 schemes were identified:

- Austria: Provisional procedure codes for new diagnostic or therapeutic methods (NUB);
- Belgium: Restricted Clinical Application for invasive medical devices and implants (Application Clinique Limité);
- England: Innovation Technology Payment (ITP), Innovation and Technology Tariff, and Commissioning through Evaluation;
- France: Hospital Program of Clinical Research (PHRC), Health Economic Research Program (PRME), Innovation Package (forfait innovation) and List of biological and anatomocytopathology innovative acts outside the nomenclature (RIHN);
- Germany: New diagnostic or therapeutic methods (Neue Untersuchungs- und Behandlungsmethoden, NUB) and Government-co-sponsored studies according to the §137e of the German Social Code Book V;
- Netherlands: Conditional funding of medical technologies within Basic Health Insurance (Voorwaardelijke toelating tot het basispakket) and small-scale experiments for the introduction of innovations (Innovatie voor kleinschalige experimenten);
- Switzerland: Provisional reimbursement of medical procedures (Leistungen in Evaluation).

Most of the schemes (n=11, 79%) are focused on coverage with evidence development. Three schemes (21%) are innovative funding programs with no requirements to generate evidence during the coverage period.

All but one program are focused primarily on medical technologies. One program (RIHN) is focused exclusively on in-vitro diagnostic tests.

Critical review of every innovative payment program is provided in the report.

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- Kathy Scott, Deputy Director, Innovation and Research, Strategy and Innovation Directorate, NHS England, UK

METHODOLOGY

European Med Tech and IVD Reimbursement Consulting Ltd. (hereafter MTRC) used its in-house expertise to identify and provide an overview of the innovative payment schemes for medical devices and in-vitro diagnostic tests in European countries.

MTRC has considered innovation payment and coverage with evidence development schemes only.

The following information was provided in relation to every innovative payment scheme: title, objective, overview, inclusion criteria, applicant, administrator and evaluator, clinical and economic requirements for the scheme, and statistics about the scheme.

The report was developed in December 2017. The only update was made in April 2018 concerning selected technologies for Innovation and Technology Payment in England in 2018/19.

The following innovative payment schemes were identified and reviewed in the Research Paper:

Country	Payment scheme	Type of the scheme	Technologies in scope
Austria	Provisional procedure codes for new diagnostic or therapeutic methods (NUB)	Coverage with evidence development	Devices
Belgium	Restricted Clinical Application for invasive medical devices and implants (Application Clinique Limité)	Coverage with evidence development	Devices
Denmark	None	-	-
England	Innovation Technology Payment (ITP)	Innovation funding	Devices
	Innovation and Technology Tariff	Innovation funding	Devices, medical apps
	Commissioning through Evaluation	Coverage with evidence development	Devices
Finland	None	-	-
France	Hospital Program of Clinical Research (Programme Hospitalier de Recherche Clinique, PHRC)	Coverage with evidence development	Devices, drugs
	Health Economic Research Program ([Programme de Recherche Medico-Economique, PRME)	Coverage with evidence development	Devices
	Innovation Package (forfait innovation)	Managed introduction / Coverage with evidence development	Devices

Country	Payment scheme	Type of the scheme	Technologies in scope
	List of biological and anatomocytopathology innovative acts outside of the nomenclature (Le référentiel des actes innovants hors nomenclature de biologie et d'anatomocytopathologie)	Coverage with evidence development	IVD tests
Germany	New diagnostic or therapeutic methods (Neue Untersuchungs- und Behandlungsmethoden, NUB)	Innovation funding	Devices, drugs
	Government-co-sponsored studies according to the §137e of the German Social Code Book V	Coverage with evidence development	Devices
Italy	None	-	-
The Netherlands	Conditional funding of medical technologies within Basic Health Insurance (Voorwaardelijke toelating tot het basispakket)	Coverage with evidence development	Devices, drugs
	Small-scale experiments for introduction of innovations (Innovatie voor kleinschalige experimenten)	Coverage with evidence development	Devices, healthcare programs
Norway	None	-	-
Spain	None	-	-
Sweden	None	-	-
Switzerland	Provisional reimbursement of medical procedures (Leistungen in Evaluation)	Coverage with evidence development	Devices, IVD tests

Details of each scheme are presented in the individual sections of the report.

Accelerated Access Pathway in the UK, as a way to implement recommendations from the Accelerated Access Review was not considered in this document because this pathway is not yet established and its configuration is not clear.

The pilot project for managed introduction of medical technologies into the Swedish health care system was not considered in this document because this pathway has not been formally established in Sweden yet.

MTRC tried to validate the findings with authorities in individual European countries who are responsible for the development of supervision of the identified innovative payment schemes. Response was received from several organizations (see the table below).

Country	Contacted organization	Response received
Austria	Ludwig Boltzmann Institute for Health Technology Assessment	Response was received
Belgium	Institut national d'assurance maladie invalidité	No response received
England	NHS England	Response was received about Innovation and Technology Tariff and Innovation and Technology Payment
France	National Authority for Health (HAS)	HAS does not provide response to requests to comment on research articles
	Ministry of Health	No response received
Germany	Institut für das Entgeltsystem im Krankenhaus GmbH	Institute does not provide response to requests to comment on research articles
	Gemeinsamer Bundesausschuss (G-BA)	No response received
The Netherlands	Nederlandse Zorgautoriteit	Response was received about small-scale experiments for the introduction of innovations
	Zorginstituut Nederland	No response received
Switzerland	Federal Office of Public Health FOPH	Response was received

AUSTRIA: PROVISIONAL CODES FOR NEW DIAGNOSTIC OR THERAPEUTIC METHODS

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 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 not sufficient to incentivize the use of the procedure, and no specific clinical study is activated. Nevertheless, this program is classified as coverage with an evidence development (CED) scheme.

Overview

In Austria, no standardized models for the innovation funding of medical devices exist. The introduction of a new procedure code requires a good level of evidence. Hospitals make applications to the Federal Ministry of Health and Women (BMGF) and applications are assessed by the LKF-Working Group who 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, Ludwig Boltzmann Institute (LBI-HTA). The BGK makes the final decision about the creation of new procedure codes.

Since 2009, it has been possible to include high-cost procedures in the field of leading-edge medicine in the procedure catalog despite insufficient evidence via a provisional procedure code. The creation of a provisional procedure code is the outcome of a standard application for a new procedure code in case a procedure is promising but evidence is regarded as insufficient.

Provisional procedure codes are grouped into existing DRGs and assigned the same DRG-points as comparable treatments, which are established in the system to determine the reimbursement tariff. This means that while the procedure is coded using the provisional code, it receives sufficient reimbursement to cover the cost, but not sufficient coverage to incentivize the use of the procedure. Provisional procedure codes in Austria can, therefore, be categorized as a CED scheme, rather than innovation funding, despite insufficient coverage.

If sufficient evidence is established until November 30th, a re-assessment takes place by the LBI-HTA. 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.

Provisional codes are included in the Austrian DRG system (LKF Modell) and are available to all hospitals that acquire approval to use them by the state health funds. In practice, however, provisional codes are often not used, which means that no evidence can be collected, and as a result, codes often stay in their provisional state for several years.

Provisional codes are listed in chapter 22 of the Austrian inpatient procedure catalog.

Inclusion criteria

For procedures to be included in the catalog, 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 not sufficient, 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 Health and Women (BMGF)	Administrator of the DRG system, collects proposals for new procedure codes, releases updated catalog of procedures annually
The LKF-Working Group	Assesses proposals, performs evaluations and makes suggestions to BGK
Federal Health Commission (BGK)	Body of the Federal Health Agency (BGA), decides upon creation of new procedure codes
Ludwig Boltzmann Institute (LBI-HTA)	Central HTA body in Austria. Prepares health technology assessment (HTA) reports on request by the LKF-Working Group

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 about the scheme

Eleven provisional procedures are included in the DRG system for 2017:

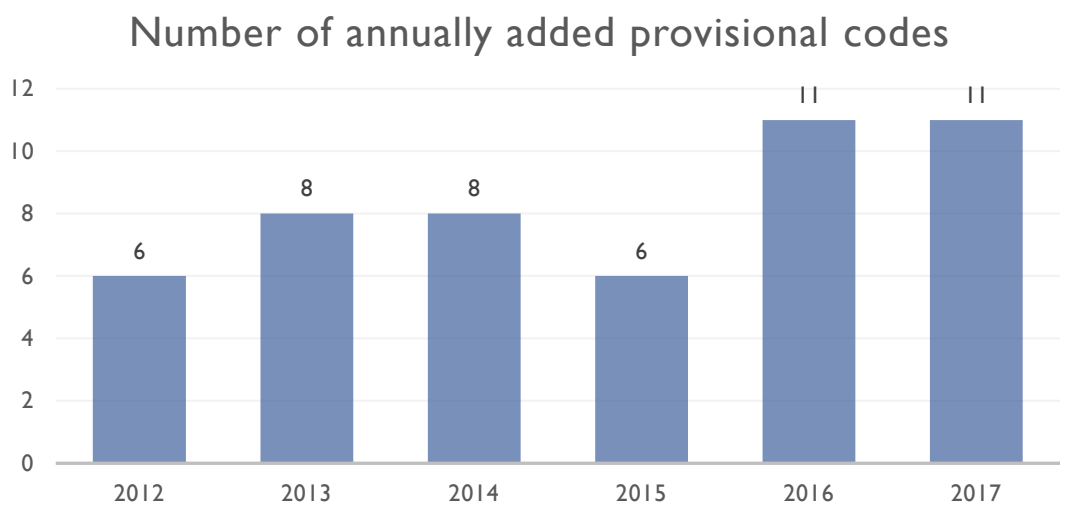
Code	Name of procedure (English)	Name of procedure (German)
XN020	Implantation of a system for cardiac contractility modulation (CCM) (Reimbursement per session)	Implantation eines Systems zur kardialen Kontraktilitätsmodulation (LE=je Sitzung)
XN030	Implantation of a stent graft in aorta ascendens (Reimbursement per session)	Implantation eines Stentgrafts in die Aorta aszendens (LE=je Sitzung)
XN040	Bronchial valve implantation (Reimbursement per session)	Ventilimplantation in das Bronchialsystem (LE=je Sitzung)
XN050	Percutaneous mitral valve clip implantation (Reimbursement per session)	Implantation eines Mitralklappenclips – perkutan (LE=je Sitzung)
XN055	Catheter-supported mitral valve replacement - transapical (Reimbursement per session)	Ersatz der Mitralklappe – kathetergestützt, transapikal (LE=je Sitzung)
XN070	Percutaneous transluminal thrombectomy of intracranial vessels (Reimbursement per session)	Perkutane transluminale Thrombektomie intrakranieller Gefäße (LE=je Sitzung)
XN080	Percutaneous transluminal angioplasty (PTA) of intracranial vessels (Reimbursement per session)	Perkutane transluminale Angioplastie (PTA) an intrakraniellen Gefäßen (LE=je Sitzung)
XN090	Percutaneous transluminal recanalization of intracranial vessels with stent implantation (Reimbursement per session)	Perkutane transluminale Rekanalisation mit Stentimplantation an intrakraniellen Gefäßen (LE=je Sitzung)
XN100	Percutaneous transluminal embolization of cerebral aneurysms by flow diverters (Reimbursement per session)	Perkutane transluminale Embolisation cerebraler Aneurysmen mittels Flow Diverter (LE=je Sitzung)
XN110	Left atrial appendage permanent embolism protection system implantation (Reimbursement per session)	Implantation eines permanenten Embolieprotektionssystems in das linke Herzohr (LE=je Sitzung)
XN120	Implantation of a completely bioresorbable stent into the coronary vessels (Reimbursement per stent)	Implantation eines vollständig bioresorbierbaren Stents in die Koronargefäße (LE=je Stent)

Break-down of provisional procedure codes in 2017 by clinical areas

In total, six procedures (55%) are from the cardiovascular field, four procedures (36%) are from the neurovascular field, and one procedure (9%) is from the pulmonary and airways field.

Number of provisional procedure codes in the past six years

The figure below shows the number of provisional codes added to coverage between years 2012 and 2017. Out of 6 procedures with a provisional status in 2012, five were still included as provisional codes in 2017.



BELGIUM: RESTRICTED CLINICAL APPLICATION FOR DEVICES

Title

Restricted Clinical Application for invasive medical devices and implants (Application Clinique Limité).

Objective

Restricted Clinical Application is intended to provide temporary (up to 3-5 years) reimbursement in a limited number of centers 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 / RIZIV). The manufacturers make 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 Nomenclature. However, a high level of clinical and economic 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, invites hospitals to participate in the scheme. At the end of the coverage period, hospitals and a relevant professional organization issue a joint report. On the basis of the report, the Commission decides about reimbursement of the device in Belgium.

The program was started in July 2014.

Inclusion criteria

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

Applicant

It is not possible to apply for the scheme. The manufacturer makes an application for inclusion in the reimbursement catalog. The scheme is one of the outcomes of a negative reimbursement evaluation.

Stakeholders involved

Stakeholder	Role
Commission of Reimbursement of Implants and Invasive Medical Devices	Decision to propose the Restricted Clinical Application scheme, determining conditions of the 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 are included into a submission dossier by the manufacturer.

Statistics about the scheme

Category	Data
Number of applications in 2016	Not relevant, as no applications are made for the program
Number of selected technologies in 2016	5

Since 2014, seven technologies were included in the Restricted Clinical Application scheme:

- Deep brain stimulation for refractory epilepsy (2016)
- Deep brain stimulation for obsessive-compulsive disorder (2016)
- Deep brain stimulation for abnormal movements (2016)
- MitraClip for mitral insufficiency (2016)
- Watchman and Amplatzer for left appendage occlusion to prevent stroke (2017)
- Ventricular assist devices (uni-, bi-ventricular) (2016)
- HepaWash for liver dialysis (2015)

Number of selected technologies for the last five years

Altogether, only seven technologies were admitted to the program: one in 2015, five in 2016, and one in 2017.

ENGLAND: COMMISSIONING THROUGH EVALUATION

Title

Commissioning Through Evaluation.

Objective

NHS England's Commissioning through Evaluation (CtE) program enables 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 represents coverage with evidence development program.

Overview

Commissioning through Evaluation is an integral part of the national commissioning process by NHS England. It does not concern procedures, commissioned locally by the Clinical Commissioning Groups.

In the process of the review of procedures for routine commissioning, NHS England can conclude that a procedure is promising, but that the evidence is not yet sufficient to routinely commission the procedure. When NHS England sees the potential to bridge the evidence gap to inform a commissioning decision, the procedure can be selected to enter into CtE program.

So, enrollment into the program starts 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 suggests a topic for CtE. The topic is 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), develops the formal proposal for the study. At the end of topic selection phase, the study is confirmed.

The next phase of the process is a recruitment phase with a selection of hospitals and the recruitment of patients. Only a limited number of hospitals is included. The number of patients in the scheme is also limited.

After the completion of the study, an External Assessment Center, commissioned by NICE, performs an analysis of the study data and in parallel performs an evidence review for the procedure. The Center and NICE jointly publish the final report of the program. NHS England should perform a repeat review of the technology and consider it for routine commissioning nationally.

The NHS England fully sponsors the studies. They typically have case series / before and after design that are organized in the form of registries. A sample size of the study can be up to 400 patients.

The study will typically last 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); final report from NICE and External Assessment Center is issued in July 2017.

Inclusion criteria

NHS England released the following inclusion criteria:

- The topic falls within NHS England's direct commissioning responsibilities for specialised services;
- The treatment or care pathway shows significant promise as a potential, future, routine, NHS treatment approach;
- A policy has been published confirming that the treatment is not routinely commissioned (NRC) or that the topic represents an area of specialised care where there are 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 will not be answered by current or planned clinical trials;
- Meaningful new outcome data can be gathered within the likely timescale of a CtE (typically 1-2 years).

Applicant

No application is made for inclusion into the scheme. The NHS England activates it in the process of review of the procedure for national commissioning.

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
Specialised 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 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

Clinical and economic requirements for the scheme

There are no defined requirements for the scheme. The procedure should be first negatively evaluated by NHS England for routine national commissioning. Procedure should have good, but not yet sufficient evidence to justify routine commissioning by NHS England. It should be possible to bridge the knowledge gap with the study (typically, using registry format).

Statistics about the scheme

As of December 2016, there were six ongoing CtE studies:

- Selective Dorsal Rhizotomy (SDR) to increase mobility in children with cerebral palsy
- Selective Internal Radiation Therapy (SIRT) for liver cancer
- Percutaneous Mitral Valve Leaflet Repair (Mitraclip) for mitral regurgitation
- Patent Foramen Ovale (PFO) Closure to prevent recurrent stroke
- Left Atrial Appendage Occlusion (LAAO) to prevent stroke
- Stereotactic Ablative Radiotherapy (SABR) for number of conditions

One additional technology is in the process of beginning the CtE program (Bionic Eye Surgery).

ENGLAND: INNOVATION AND TECHNOLOGY TARIFF

Title

Innovation and Technology Tariff.

Objective

The Innovation and Technology Tariff (ITT) was introduced to incentivize the adoption and spread of transformational innovation in the NHS. The scheme is classified as an innovation funding scheme.

Overview

The scope of the program is on already established technologies, from which NHS can benefit. Proposed technologies should meet requirements/criteria for the call for applications (see below). Selection, in general, was made in connection with 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 web-site by the NHS England. However, currently, the responsible entity for the program is Innovation and Research Unit at NHS England. NHS England makes 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 are reimbursed via a so-called "zero cost model". In this model, providers order the innovations directly from the supplier at no cost and NHS England reimburses the supplier directly. Cost of the implementation of innovation is not covered.

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 utilized 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 involves capital investment or set-up costs is unlikely to be applicable for a national tariff.

Applicant

Manufacturer (developer of the technology) makes an application.

Stakeholders involved

Stakeholder	Role
NHS Innovation Accelerator	Call for application, collection of proposals,
NHS England	Review of the proposals, overview supervision of the scheme Ultimate funding decision Funding of the method within 2-year period
System partners (including Arm's Length Bodies, Clinicians)	Input into the decision-making process
Academic Health Science Networks (AHSNs)	Support for implementation of innovation

Clinical and economic requirements for the scheme

One of the main requirements of the program is that the technology should be established, although no specifics are provided.

In the public consultation in relation to the initiation of the scheme, NHS England and NHS Improvement received feedback that the Innovation and Technology tariff should be connected to NICE medical technology reviews. However, no formal connection has been established.

Statistics about the scheme

Category	Data
Number of applications in 2016	Number of applications is not known
Number of selected technologies in 2016	In total, six technologies were selected for funding in 2016 (start in April 2017)

The following technologies were selected for funding starting from April 2017:

- Guided mediolateral for episiotomy to minimize the risk of obstetric and anal sphincter injury;
- A non-injectable arterial line connector designed to prevent a reduction of bacterial contamination and accidental administration of medication;

- An innovative endotracheal tube designed to prevent a ventilated associated pneumonia in critically ill patients;
- Web-based applications for the self-management of chronic obstructive pulmonary disease;
- Frozen fecal microbiota transplantation (FMT) for recurrent Clostridium difficile infection;
- Treatment of lower urinary tract symptoms of benign prostatic hyperplasia as a day case.

Five technologies (except for the prostate treatment Urolift) received a national, unbundled (paid on top of HRG) tariff, which will be paid by NHS England irrespective of the commissioning status of the methods. The tariff will be paid on top of the HRG payment. For Urolift, HRGs were already available in the National Tariff Payment System.

The specifics of the payment are provided in the table below (extract from the National Tariff for 2017/19).

ITT Code	ITT Category	How it will operate	Current reference price (£)	Mandatory Price (£)
ITT-01	Guided mediolateral for episiotomoy to minimize the risk of obstetric and anal sphincter injury	Locally reported and charged per use of Episcissors	16	n/a
ITT-02	A non-injectable arterial line connector designed to prevent a bacterial contamination and accidental administration of medication	Locally reported and charged per device	2	n/a
ITT-03	An innovative endotracheal tube designed to prevent a ventilated associated pneumonia in critically ill patients	Locally reported and charged per device	150	n/a
ITT-04	Web-based applications for the self-management of chronic obstructive pulmonary disease	Locally reported and charged per patient registration	20	n/a
ITT-05	Frozen faecal microbiota transplantation (FMT) for recurrent Clostridium difficile infection	Locally reported and charged per patient use	95	n/a
ITT-06	Treatment of lower urinary tract symptoms of benign prostatic hyperplasia as a day case	Reported via SUS and charged per spell	n/a n/a	HRG: LB70C HRG: LB70D

Further details of the reimbursement arrangements and a rationale for the selection of initial topics for funding in 2017 are provided here.

In parallel, but separately from the ITT, NHS England is centrally funding the 7th theme "Identification and measurement of atrial fibrillation through mobile ECG technology".

ENGLAND: INNOVATION TECHNOLOGY PAYMENT

Title

Innovation and Technology Payment (ITP).

Objective

The Innovation and Technology Payment (ITP) builds on the Innovation and Technology Tariff (ITT) and aims 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.

Overview

The ITP is looking to support medical devices, digital platforms, and technologies. The program is not suitable for pharmaceutical products or research projects. The ITP is specifically focused on low-cost innovations that can deliver significant patient outcomes and cost savings to NHS.

NHS England identified technologies via a competitive process and determined ways to support these innovations, either via reimbursement for usage or by the central procurement of the technologies.

The program is developed in collaboration between NHS England, Academic Health Science Networks, system partners and experts. The program is managed by the NHS England's Innovation and Research Unit.

Call for proposals launches in June. Applications were received from July until September (8th of September in 2017). Two application-sifting rounds take place in October and November. A decision panel selects the final cohort for further due diligence and commercial discussions in December. In March, the definition of the Innovation Technology Payment tariff is finalised. The scheme is launched in April (the start of the financial year in England).

The program was launched in 2017, with first funding starting from April 2018. The funding will be available for the period of one year, after which the program and funded themes will be reviewed.

Further details of the program are available in the 2017 Call for Proposals document.

Inclusion criteria

The following inclusion criteria are applicable:

- Has a demonstrated (in practice – not theoretically or hypothetically) benefit to the NHS, through increasing quality, health and wellbeing and creating efficiency;
- Are at the correct phase of innovation – as such, applicants are required to show that their innovation is supported by a robust evidence base and is ready to be diffused widely across the NHS;

- Can 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;
- Currently face financial or procurement barriers to wider adoption and diffusion in the NHS that could be overcome with central financial support;
- Are low cost. This program is targeted at innovations that can be diffused quickly and at low cost;
- Have satisfied all necessary regulatory, intellectual property and ethical frameworks within the applicant's host country.

Priority areas are determined in Next Steps in the Five Year Forward View and NHS Business Plan.

Applicant

Applicants can be from any of the following: healthcare, academic, and the commercial or voluntary sectors.

Stakeholders involved

The following stakeholders are involved (from experience of submissions in 2016).

Stakeholder	Role
NHS England's Innovation and Research Unit	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 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 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 National Director Strategy and Innovation, Tara Donnelly, Chief Office 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.

Clinical and economic requirements for the scheme

Accompanying documents for the scheme specify that applications will need to include robust evidence to demonstrate that their innovation has a genuinely high impact, is affordable and is at the correct level of maturity and relevance for widespread diffusion. However, details are not available.

Applicants will, therefore, need to describe efforts that have been made to widen the adoption of their innovation in the NHS and the barriers that they and NHS organizations have encountered.

Statistics about the scheme

In April 2018, NHS England announced that four technologies were selected for the national funding by NHS England in 2018/19, including:

- 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 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.

FRANCE: HOSPITAL PROGRAM OF CLINICAL RESEARCH, PHRC

Title

Hospital Program of Clinical Research (Programme Hospitalier de Recherche Clinique, PHRC).

Objective

PHRC aims to assess the feasibility, efficacy, and safety of innovation methods via government-sponsored research in French hospitals. This program is considered to be the first step in the evaluation of the innovative technologies in France. Another important objective of the program is to promote research at French hospitals. The scheme is classified as coverage with evidence development program.

The scheme covers drugs, medical technologies, and other methods. It very rarely includes in-vitro diagnostic tests.

Overview

With the program, the Ministry of Health provides a dedicated budget for funding the of clinical research programs at French hospitals. This budget (MIGAC) is paid in addition to funds allocated within statutory health insurance to the hospital for the provision of general care. The program is applicable to drugs and medical technologies.

In the process, the Ministry of Health makes a call 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. Pre-selection of the application is made by June by responsible parties (this differs depending on the type of PHRC call). During the July-September period, applicants need to submit a full protocol. During November-December, a final decision about selection of research projects is made. From the beginning of the next year, researchers can receive funding for the study.

Typically, PHRC study would be performed in a single center. Design of the studies may vary from small-scale non-controlled studies to RCTs. Duration is typically up to 2 years.

The government fully sponsors the program. Physicians are responsible for developing the protocol. The manufacturer does not have any formal control over the design and execution of the study.

PHRC is available in three calls for proposals:

- PHRC-N (national) – covers all diseases except for cancer and infections, related to HIV, HBV, and HCV
    - Welcomes large international projects, where PHRC-N can fund French part
    - In 2016, 95 projects were selected with average budget of 634,741 euros
- PHRC-K (cancer) – covers cancer
    - In 2016, 42 projects were selected

- PHRC-I (interregional) - covers all diseases except for infections, related to HIV, HBV, and HCV
    - For 2017 campaign, the total budget of 27 million euros was allocated
    - In 2016, 105 projects were selected with an average budget of 235,283 euros

Inclusion criteria

Each year, the Ministry of Health determines priority areas for the PHRC program. Studies focused on priority areas receive a higher rating and have higher chances of obtaining funding.

The latest (from 2015 call for applications) priority criteria for the program include:

- To perform research in primary care;
- Assessing safety, tolerance or feasibility of the use of health technologies in humans;
- Measuring the effectiveness of health technologies using controlled randomized or non-randomized methods.

There are specific selection criteria they are applied at different stages of the study selections.

- Eligibility criteria at the pre-selection stage
    - Justify direct impact of results of the study of care of patients;
    - Demonstrate that methods of the research will provide data with high level of evidence;
- Medico-economic projects are only eligible within Phase III framework
    - The main objective is to demonstrate relative clinical effectiveness of medical technology;
    - The primary objective is clinical, and health economic objective is secondary in the research;
    - Health economic section is written by a recognized health economist, according to the requirements defined by the French National Authority for Health (HAS).

For the inter-regional PHRC call for proposals, further specific selection criteria are applied, including:

- An emerging team proposes project with no prior PHRC funding;
- Involving at least two centers
    - This is done with the objective of promoting interregional collaboration;
- Centers are mainly present (at least 50%) in the geographical region for this particular supervising organization;
- Coordinating center is located in the geographical region for this particular supervising organization;
- Results of the study will directly modify management of patients
    - This also includes use of relevant methodology to provide a solid proof of the impact;
- Maximum amount of funding does not exceed 300,000 euros;
- Medico-economic projects are only eligible within Phase III framework;

The study may be performed even for non-CE-marked technologies.

Applicant

Researchers within hospitals.

Stakeholders involved

The following stakeholders are involved.

Stakeholder	Role
Ministry of Health	Determines scope and priorities of the program in the annual circular Provides funding for the research program
Interregional Groups of Clinical Research and Innovation (GIRCI)	Performs collection, review, awarding, funding (distributing funds allocated from Ministry of Health), and management of the PHRC Interregional (PHRC-I)
French National Cancer Institute (INCA)	Performs collection, review, awarding, funding (distributing funds allocated from Ministry of Health), and management of the PHRC program with focus on cancer (PHRC-K)
Researchers within hospitals	File letter of intent, submit full proposal for research funding, perform the study
National Agency for Research (ANR)	Maintains the website with list of all open calls for proposals for research funding

Clinical and economic requirements for the scheme

There are no specific clinical or economic requirements for this scheme.

Statistics about the scheme

Category	Data
Number of applications in 2016	Not known
Number of selected technologies in 2016	95 projects for PHRC-national call including drugs and devices, including 27 studies (28%; including one study of IVD test) of procedures and devices, 53 studies (56%) of drugs, and 15 studies (16%) of other methods (e.g. non-medical, etc.) 105 projects for PHRC-interregional call including drugs and devices 42 projects for PHRC-cancer call including drugs and devices

The list of PHRC-National projects related to medical technologies, including budget, is presented below.

Title in French	Title in English	Code	Budget
Devenir à long terme neurologique et respiratoire des patients atteints de SDRA ventilés avec deux stratégies d'oxygénation	Liberal oxygenation versus conservative oxygenation in ARDS	PHRCN-16-0414	570,256 €
Qualité de vie et Dialyse incrémentale chez les patients fragiles	Quality of life and incremental dialysis in fragile patients	PHRCN-16-0488	331,496 €
Le ballonnet pour l'induction du travail chez les femmes obèses à terme (The BigW trial)	Induction of labor in obese women with a balloon (The BigW trial)	PHRCN-16-0686	573,348 €
IRM du poumon dans le suivi de la mucoviscidose	MRI of the lung in the follow-up of cystic fibrosis	PHRCN-16-0480	769,195 €
Evaluation de l'impact du PET-scan dans la prise en charge des patients ayant une infection bactériémique à Staphylococcus aureus	Evaluation of the impact of PET-scan in the management of patients with Staphylococcus aureus infection	PHRCN-16-0298	572,462 €
Evaluation de l'embolisation des reins polykystiques comme alternative à la néphrectomie avant transplantation rénale.	Embolization of polycystic kidneys as an alternative to nephrectomy before renal transplantation	PHRCN-16-0513	391,636 €
Etude des effets bénéfiques de la ventilation mécanique durant la chirurgie cardiaque avec circulation extracorporelle sur la survenue des infections postopératoires	Study of the beneficial effects of mechanical ventilation during cardiac surgery with extracorporeal circulation on the occurrence of postoperative infections	PHRCN-16-0367	881,881 €
Évaluation d'une stratégie guidée par l'imagerie non invasive par rapport à la coronarographie systématique chez les patients âgés avec Ischémie	Evaluation of a strategy guided by non-invasive imaging versus systematic coronary angioplasty in elderly patients with ischemia	PHRCN-16-0680	1,180,409 €
Etude multicentrique randomisée du système de réparation percutané de valve mitrale MITRACLIP® dans la prise en charge des Insuffisances Mitrales primitives chez des patients éligibles à une chirurgie mitrale à Risque élevé	Multicentre study of MITRACLIP® transcatheter mitral valve repair in patients with severe primary mitral regurgitation eligible for high-risk surgery	PHRCN-16-0295	1,176,122 €
Evaluation de la stimulation occipitale dans les névralgies occipitales réfractaires	Occipital nerve stimulation for the treatment of refractory occipital neuralgia	PHRCN-16-0413	556,358 €
Dépistage de la prééclampsie et de la restriction de croissance in utero au premier trimestre de la grossesse par angiographie Doppler3D. Etude prospective observationnelle chez des femmes nullipares.	First-trimester 3-dimensional power Doppler of the uteroplacental circulation space: a potential screening method for preeclampsia	PHRCN-16-0567	588,313 €

Title in French	Title in English	Code	Budget
Etude randomisée évaluant la chirurgie bariatrique comme traitement de la stéatohépatite non alcoolique sévère avec fibrose hépatique avancée chez le patient obèse non sévère	A randomized study evaluating bariatric surgery as a treatment for severe non-alcoholic steatohepatitis with advanced hepatic fibrosis in patients with non-severe obesity	PHRCN-16-0478	410,994 €
Ventilation mécanique protectrice pour chirurgie abdominale urgente: étude multicentrique prospective randomisée	Mechanical ventilation in emergency abdominal surgery: prospective randomized multicentre study	PHRCN-16-0027	555,398 €
Marqueurs stéréo-électroencéphalographiques d'épileptogénicité : valeur pronostique de l'analyse quantitative de crises par l'Index d'Epileptogenicité dans la prise en charge rationnelle des épilepsies pharmacorésistantes associées aux dysplasies corticales focales.	Stereo-electroencephalographic markers of epileptogenicity: the prognostic value of the quantitative analysis of seizures by the Epileptogenicity Index in the rational management of drug-resistant epilepsies associated with focal cortical dysplasia	PHRCN-16-0685	532,634 €
Application combinée du post-conditionnement ischémique intra-coronaire et du post-conditionnement à distance dans l'infarctus aigu du myocarde : une étude clinique multicentrique, randomisée, contrôlée.	Combined application of intracoronary ischemic post-conditioning and post-conditioning in acute myocardial infarction: a multicenter, randomized, controlled clinical trial	PHRCN-16-0354	1,058,961 €
Impact des canules nasales à haut débit dans l'asthme aigu grave chez les enfants	Impact of high-throughput nasal cannula in severe acute asthma in children	PHRCN-16-0489	371,379 €
Évaluation de l'utilisation première de l'imagerie par résonance magnétique pour le diagnostic de coronaropathie causale de dysfonction ventriculaire gauche.	Evaluation of the primary use of magnetic resonance imaging for the diagnosis of coronary artery disease of left ventricular dysfunction	PHRCN-16-0181	463,072 €
Essai randomisé comparant l'efficacité du cerclage chirurgical dans la prévention du décollement de rétine dans le Syndrome de Stickler génétiquement confirmé	Randomized trial comparing the effectiveness of surgical cerclage strap in the prevention of retinal detachment in genetically confirmed Stickler Syndrome	PHRCN-16-0220	597,181 €
Chirurgie valvulaire ultraprécoce versus traitement conventionnel dans la prévention du risque embolique chez les patients présentant une endocardite à haut risque embolique : un essai randomisé.	Ultraspecific valve surgery versus conventional treatment in the prevention of embolic risk in patients with endocarditis and a high risk of embolism: a randomized trial	PHRCN-16-0240	628,087 €
Comparaison de 2 stratégies d'initiation de l'épuration extra-rénale en réanimation, essai contrôlé randomisé.	Comparison of 2 strategies of initiation of extra-renal purification in resuscitation, randomized controlled trial	PHRCN-16-0278	584,980 €

Title in French	Title in English	Code	Budget
Etude randomisée du transfert embryonnaire différé versus frais dans une population de patientes infertiles en FIV-ICSI	Randomized study of delayed frozen versus fresh embryonic transfer in a population of infertile IVF/ICSI patients	PHRCN-16-0313	1,046,559 €
Comparaison de l'oxygénothérapie à haut débit et de l'oxygénothérapie conventionnelle sur la durée de l'assistance ventilatoire au cours de l'insuffisance respiratoire aiguë hypercapnique : Etude randomisée contrôlée multicentrique	Comparison of high-flow oxygen therapy and conventional oxygen therapy and non-invasive ventilaton during acute hypercapnic respiratory failure: multicenter controlled randomized controlled trial	PHRCN-16-0383	443,238 €
Efficacité de l'aponévrotomie percutanée à l'aiguille pour maladie de Dupuytren : une étude multicentrique, randomisée, de non infériorité, comparative avec la chirurgie	Needle aponeurotomy for Dupuytren contracture: a multicenter, randomized, non-inferiority, comparative study with surgery	PHRCN-16-0393	675,610 €
Utilisation d'une PCR multiplex respiratoire pour réduire l'exposition aux antibiotiques au cours de la pneumonie aigue communautaire grave de l'adulte (essai VIRCAP): essai contrôlé randomisé multicentrique, en groupe parallèle, en ouvert	Use of respiratory multiplex PCR to reduce exposure to antibiotics in severe adult acute adult pneumonia (VIRCAP test): randomized controlled trial, multicenter, parallel group, open-label	PHRCN-16-0595	671,335 €
ECT dans la schizophrénie Ultra-Résistante	ECT in ultra-resistant schizophrenia	PHRCN-16-0401	220,541 €
Comparaison randomisée entre la réparation valvulaire précoce et "l'attente armée" dans l'insuffisance mitrale sévère asymptomatique dégénérative par prolapsus	Comparison between early and longer valvular repair in cases of severe asymptomatic degenerative asymptomatic prolapse	PHRCN-16-0433	737,930 €
Evaluation comparative de la chirurgie mini-invasive dite "Tubéroplastie tibiale" versus la technique conventionnelle à ciel ouvert pour le traitement des fractures du plateau tibial.	Comparative evaluation of minimally invasive surgery known as "tibial tuberoplasty" versus the conventional open-top technique for the treatment of the tibial plateau fractures.	PHRCN-16-0484	691,687 €

Break-down of selected technologies in 2016 by clinical area (devices only)

The most common technological areas were pulmonary and airways (19%), cardiovascular (15%) and imaging (15%).

Technological area	Number	Percentage
Pulmonary and Airways	5	19%
Cardiovascular	4	15%
Imaging	4	15%
Nephrology and Urology	3	11%

Technological area	Number	Percentage
Obstetrics and Gynecology	3	11%
Neurology and neurosurgery	2	7%
In-vitro diagnostics	1	4%
Neuromodulation	1	4%
Obesity surgery	1	4%
Ophthalmology	1	4%
Orthopedics	1	4%
Other	1	4%

Number of selected technologies for the last five years (drugs and devices)

A number of selected technologies for 2012-2016 by type of the PHRC program (drugs and devices) is presented in the table below.

Type of program	2012	2013	2014	2015	2016
PHRC-K	56	44	43	37	42
PHRC-N	112	86	89	103	95
PHRC-I	119	101	82	96	105
PHRC Total	287	231	214	236	242

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.

Overview

PRME is a coverage with evidence development program in France. The program includes medical technologies only (drugs are excluded).

In the process, the Ministry of Health makes a call 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. Pre-selection of the application is made by June by responsible parties (this differs depending on the type of PHRC call). During 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.

It is considered to be the next step in complexity and objective after PHRC program. The program only considers products for which their clinical effectiveness and safety have been demonstrated before in PHRC, 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 present, which would enable reimbursement either via DRG for the procedure described using CCAM code or via add-on reimbursement for implants and invasive devices via LPPR program.

The government fully sponsors the program.

The design of the study is typically a randomized controlled trial combined with a health economic assessment. The typical duration is up to 2 years. All projects should study health economic consequences according to the standards defined by HAS, which is typically in the form of cost-effectiveness analysis. A health economist and methodologist should be systematically involved in the development of the protocol. The study should have the design of a randomized controlled trial.

Specifics of the study design include:

- The comparator should be a relevant standard of care in France. If multiple comparators exist, they should be present in the study;
- Health economic study is mandatory and should follow methodological requirements, outlines by National Authority for Health (HAS);
- Projects should be multicenter projects and include a minimum of 5 and a maximum 10 centers;
- Allocation budget should explicitly cover the additional cost of the innovation;
- If initiation of the project is unjustifiably delayed, this may result in 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 efficiency of technology for HAS;
- "Care pathway" dimension to compare effectiveness of management practice in real life vs. standard of care.

There are two calls for proposals

- PRME National
- PRME Cancer

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

Inclusion criteria

The following inclusion criteria for the program exist:

- Safety and efficacy of technology have been previously validated in clinical research;
- Project must meet the following characteristics: includes cost-utility analysis; comparator reflects currently recommended standard of care when major budget impact is anticipated; formal BIA should be performed; involved institutions should provide all necessary cost data to successfully complete project; project should preferably be multicentered;
- Technology should be CE-marked;
- Technology should optimize care pathway;
- Project should meet the following characteristics: when quantity and quality of data permits, available data shall be collected in the form of systematic literature review; when relevant data are not available, pragmatic quasi-experimental studies and the use of medico-economic database can be considered; perform budget impact analysis when necessary.

Projects on technologies that were previously evaluated by HAS should not be considered in the PRME program unless they offer comparative validation of clinical effectiveness.

Applicant

Researchers within hospitals.

Stakeholders involved

The following stakeholders are involved.

Stakeholder	Role
Ministry of Health	Determines 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 development of the letter of intent
Institutional Jury for pre-selection of the applications	Includes representatives from 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
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 letter of intent, submit full proposal for research funding, perform the study
National Agency for Research (ANR)	Maintains the website with list of all open calls for proposals for research funding

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 randomized controlled trial.

Statistics about the scheme

Category	Data
Number of applications in 2016	Now known
Number of selected technologies in 2016	Seven projects in PRME program (6 for medical procedures) Two projects for PRME-Cancer program

In 2016, there were seven projects awarded in total in the non-cancer field (PRME-N), including 6 (86%) for medical procedures:

- Therapeutic games in mental disorders;
- Management in primary care of patients with high cardiovascular risk based on screening of the asymptomatic obliterative arteriopathy of the lower limbs by the Systolic Pressure Index (IPS);
- NeLLY service in not dialyzed chronic kidney failure patients;

- Aspirational thrombectomy for stoke;
- AlfaPump for refractory ascites in cirrhotic patients;
- Detection of obstructive sleep apnea in obese patients in medical laboratories and attending physicians.

There were two projects awarded in the cancer field (PRME-K), including:

- Innovative Biology Network with evaluation of innovative molecular biology oncological markers on the RIHN List (The repository of innovative acts outside the nomenclature of biology and anatomocytopathology);
- Comparison of brachytherapy and stereotactic radiotherapy for erectile dysfunction in prostate cancer with good prognosis.

Number of selected technologies for the last five years

A number of selected technologies for 2012-2016 by type of the PRME program is presented below.

Type of program	2012	2013	2014	2015	2016
PRME	7	5	11	8	7
PRME-K	3	2	4	4	2
PRME Total	10	7	15	12	9

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 with features of managed introduction.

Overview

Innovation Package / forfait innovation is the most advanced coverage with evidence development program in France. The program is only focused on medical devices and procedures.

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

The whole process of the review of applications takes 105 days.

There is limited experience with the program to date.

Importantly, this program should not be viewed as primarily an evidence generation program because it combined coverage with evidence development with the managed introduction of the technology.

The sample size for Innovation Package 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 impact is about €3,600,000).

The budget of the study is developed in an "all-inclusive" manner.

These are the following sources of financing:

- Flat rate payment per patient provided by the state for innovation treatment arm
    - Was determined at the level of €6,047 for high intensity focused ultrasound for prostate adenocarcinoma;
    - Was determined at the level of €95,897 for Argus II for retinopathy;
- Reimbursement of intervention in the control arm via normal social security mechanism;
- Financing of research framework (protocol, analysis) of the study by applicant;

After completion of the program, it should be possible to make a decision about sufficient expected benefits for a studied method to enable reimbursement either via DRG for the procedure described using CCAM code or via add-on reimbursement for implants and invasive devices via LPPR program.

Inclusion criteria

Ministry of Health established the following mandatory criteria:

- Innovative character of technology
  - Not a simple technological evolution;
  - Early phase of diffusion;
  - Characterized risks for patients;
  - Major clinical benefits;
- Proposal of a relevant study
  - Proposed clinical or medico-economic study makes it possible to collect all missing data in order to establish 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 relevance of French state-sponsored study;
  - Feasibility of proposed study seems reasonable given the proposed protocol and budget;

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

Applicant

The manufacturer makes an application.

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 key contribution about clinical protocol

Clinical and economic requirements for the scheme

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

Statistics about the scheme

As of December 2017, only three methods were enrolled into assessment within Innovation Package / forfait innovation framework: Argus II for retinopathy, high intensity focused ultrasound for prostate adenocarcinoma and subretinal implant RETINA IMPLANT Alpha AMS.

Data about the number of submissions and awarded technologies are presented in the table below.

Status	2015	2016	2017
Number of submitted dossiers	1	3	9
Number of accepted dossiers	0	2	5
Number of technologies selected	0	1	2

FRANCE: LIST OF BIOLOGICAL AND ANATOMOCYTOPATHOLOGY INNOVATIVE ACTS

Title

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

Objective

The objective of the scheme is to provide temporary funding for innovative in-vitro diagnostic tests unless evidence is sufficient to incorporate them into the Nomenclature of medical biological 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 tests in Europe.

In France, IVD tests, which are eligible for reimbursement within statutory health insurance, shall be included in NABM Nomenclature. Only well-established and validated tests are allowed for inclusion into the NABM 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 into NABM Nomenclature. Historically, innovative IVD tests were included into 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.

The RIHN List consists of two parts: truly innovative tests and a supplemental list of left-over and no longer innovative tests. Funding of the tests is performed from the budget for research and innovation (MIGAC), which is distributed to hospitals from the Ministry of Health. The Ministry of Health is responsible for the update of the RIHN List. The recent call for applications was in October 2017. Applications for the Lists are started in September, and an updated List is released in March of the following year.

IVD tests are included 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. As of December 2017, no single test was transferred from the RIHN List to the NABM Nomenclature. The future of the supplementary list of left-over tests is not clear: they either should be integrated into NABM Nomenclature or deleted from the RIHN List.

Inclusion criteria

The following criteria for enlisting in the RIHN List exist:

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

Applicant

The manufacturer or other stakeholders can make an application.

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)	Clinical and economic evaluation of the dossiers
Other governmental and independent organizations (HAS, INCA, CNAMTS)	Review of the proposals

Clinical and economic requirements for the scheme

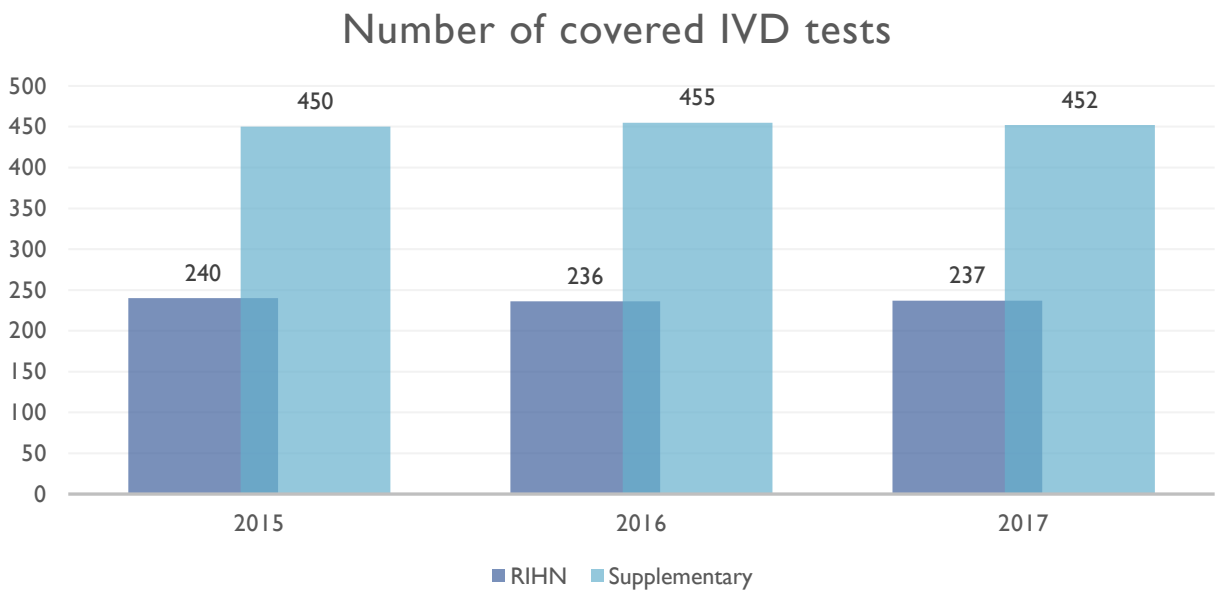
The submitted tests should be in the post-translational research phase, but clinical value, economic value, and analytical validation should not have been performed yet. As a result, there are no strict clinical and economic requirements for inclusion into the List.

Statistics about the scheme

In 2017, there were 237 tests in the RIHN List and 452 tests in a supplementary list of left-over tests.

Number of selected technologies for the last five years

Data about the number of IVD tests in the RIHN and supplementary Lists are presented in the figure below.



GERMANY: INNOVATION FUNDING FOR NEW DIAGNOSTIC OR THERAPEUTIC METHODS

Title

Innovation funding for new diagnostic or therapeutic methods (Neue Untersuchungs- und Behandlungsmethoden; NUB).

Objective

Innovation funding for new diagnostic or therapeutic methods was introduced to incentivize the use of innovative technologies while cost-data is collected and analyzed before the technology is included into the DRG system. The scheme is classified as innovation funding scheme.

Overview

The scope of the program is innovative technologies causing significant extra costs that are not covered by existing DRG tariffs. The selection of technologies is made by the Institute for the Hospital Remuneration System (InEK) according to the inclusion criteria (see below). A positive decision by InEK does not indicate that reimbursement is provided. Rather, it gives applying hospitals permission to enter into negotiations with local healthcare payers (Sickness Funds). Applications must be submitted separately by every hospital, and NUB funding will only be available to hospitals that negotiated successfully. The amount of NUB funding is not decided by InEK but determined through negotiations. Each NUB funding agreement is only valid for one year but can be renewed annually.

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 take place between April and June. The whole process from application until reimbursement requires around eight months.

The InEK publishes the results of the NUB assessment as one of 4 possible statuses.

#	Status	Implication of status
1	NUB-criteria fulfilled	The method fulfills the requirements for NUB funding. Hospitals that applied can enter 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 fulfill the requirements. The hospital cannot negotiate reimbursement with Sickness Funds. Products that have received this status have rarely received category one later.
3	Not processed by InEK	InEK did not have time to review the application. The hospital may negotiate reimbursement with Sickness Funds and make an agreement 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.

An additional procedural rule exists for procedures including the use of so-called "high-risk medical products" (i.e., class IIb or III, active implantable and especially invasive products). Since 2016, these procedures must undergo an 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 hospital making the first application for such a procedure must send additional information to the G-BA who assesses it with support by the Institute for Quality and Efficiency in Healthcare (IQWiG). If existing scientific evidence is not sufficient, the G-BA might induce a clinical study which it co-sponsors together with the manufacturer.

According to § 137h (6) SGB V, manufacturers can request a judgment by the G-BA on whether their product classifies as a high-risk or especially invasive product. This possibility has been used ten times up to the present, and in six cases, the procedure in question was not eligible for the § 137h SGB V framework, in three cases it was eligible, and one consultation was not completed.

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 (i.e., in use for a maximum of four years);
- The method causes significant extra costs that exceed or account for a significant proportion of the standard deviation of the DRG tariff;
- The calculation of costs is plausible;
- The method leads to imbalance in payment.

Applicant

Hospitals make applications.

Stakeholders involved

Stakeholder	Role
Institute for the Hospital Remuneration System (InEK)	Provision of application form, collection, and review of applications, decision about eligibility for NUB funding, monitoring of NUB utilization
Federal Joint Committee (G-BA)	Performs benefit assessment for methods using highly invasive devices
Institute for Quality and Efficiency in Healthcare (IQWiG)	Producing health technology assessments (HTA) for methods with highly invasive devices on request by the G-BA

Clinical and economic requirements for the scheme

No economic and clinical requirements exist for inclusion into the NUB innovation funding scheme. However, in relatively rare cases, a method that is based on a high-risk device will trigger an early benefit assessment by the G-BA. This rule applies if the following criteria are fulfilled:

- Method represents a new theoretic-scientific concept;

- Method is based on a medical device of risk classes IIb and III (especially invasive);
- It is the first NUB funding application for the method by a hospital.

Statistics about the scheme

Before the deadline on October 31st, 2016, a total of 36,675 requests for NUB funding in 2017, representing 686 unique procedures, were submitted to InEK. Positive status was given to 154 (22%), including 66 (10% from initially submitted and 43% of all approved technologies) technologies based on medical devices. Hospitals that sent a request for these technologies could negotiate innovation funding with sickness funds in 2017. On average (mean), 49 hospitals sent a request for innovation funding for medical technologies, ranging from 1 to 411.

The full overview of NUB applications for the year 2017 is available on InEK's website.

Category	Data for 2017
Number of total applications in 2016 (drugs and devices)	36,675
Number of technologies applied for (drugs and devices)	686
Number of technologies applied for (devices only, % of the total applications)	465 (68%)
Number of technologies that received status 1 (drugs and devices)	154
Number of technologies that received status 1 (devices only, % of the total approved applications)	66 (10%)

With support by IQWiG, the G-BA has reviewed eight innovation funding requests in context with high-risk devices according to §137h SGB V in 2016. Six of them showed neither a benefit nor a potential benefit and the G-BA could decide about the exclusion of the methods as a benefit in the inpatient sector. Two methods were considered to be potentially beneficial, but a final decision will require more evidence:

- Ultrasound-controlled high intensity focused ultrasound in patients with leiomyoma of the uterus;
- Ultrasound-guided high intensity focused ultrasound in patients with liver cell carcinoma who are not treatable with surgery;

The G-BA suggested the conduction of a co-funded study but manufacturers did not agree to cover the overhead costs, and therefore no study directives were released.

In 2017, no single high-risk device met the criteria for early benefit assessment.

All decisions made by the G-BA in relation to § 137h SGB V are available here.

List of selected technologies in 2016

In total, 66 procedures fulfilled the criteria for NUB funding and received status 1 in January 2017. For 50 of them, innovation funding had been requested in previous years.

Procedure (English)	Procedure (German)
Insertion of covered stents with bioactive surface into peripheral vessels	Einlage beschichteter (gecoverter) Stents mit bioaktiver Oberfläche für periphere Gefäße1
Implantation of an intracardiac pulse generator	Implantation eines intrakardialen Pulsgenerators
The automated low-flow ascites pump	Aszitesbehandlung mittels einer vollimplantierbaren Pumpe
Covered endoprostheses with bioactive surface for dialysis shunt revision	Gecoverte Endoprothesen mit bioaktiver Oberfläche zur Dialyse- Shunt-Revision1
Hemodynamically effective implant for the endovascular treatment of intracranial aneurysms and cerebral vasculature	Hämodynamisch wirksames Implantat zur endovaskulären Behandlung intrakranieller Aneurysmen und hirnversorgender Halsgefäße
EndoBarrier for the treatment of adiposity and type 2 diabetes	Endobarriere zur Behandlung adipöser Typ-2-Diabetiker
Percutaneous mitral valve annulorrhaphy with clasp	Perkutane Mitralklappenanulorrhaphie mit Spange
Intra-aneurysmal hemodynamically effective implant for endovascular treatment of intracranial aneurysms	Intraaneurysmales hämodynamisch wirksames Implantat zur endovaskulären Behandlung intrakranieller Aneurysmen
Endovascular installation of an inner AV shunt using magnetically guided RF energy	Endovaskuläre Anlage eines inneren AV-Shunts mittels magnetgeführter Hochfrequenzenergie
Endovascular mitral valve annuloplasty with annuloplasty band	Endovaskuläre Mitralklappenanuloplastik mit Anuloplastie-Band
Endovascular implantation of an extracorporeal centrifugal pump for circulatory support	Endovaskuläre Implantation einer extrakorporalen Zentrifugal- Pumpe zur Kreislaufunterstützung
Catheter-based implant for the treatment of left ventricular heart failure	Katheterbasiertes Implantat zur Behandlung linksventrikulärer kardialer Motilitätsstörungen
Transapical mitral valve repair by implantation of Neochordae (PTFE)	Transapikale Mitralklappenrekonstruktion durch Implantation von Neochordae (PTFE)
Bronchoscopic lung volume reduction by application of polymer foam	Lungenvolumenreduktion mittels bronchoskopischer Applikation von Polymerschaum
Implantation of a gastric pacemaker	Implantation eines Magenschrittmachers
Total Temporomandibular Joint (TMJ) Replacement	Kiefergelenkendoprothese (Totalersatz)
Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnea Syndrome (OSAS)	Hypoglossusnerv-Stimulationssystem zur Behandlung des obstruktiven Schlafapnoe-Syndroms (OSAS)
Transapical extracorporeal centrifugal pump implantation for circulatory support	Transapikale Implantation einer extrakorporalen Zentrifugal-Pumpe zur Kreislaufunterstützung
Transpericardial left atrial appendage closure	Vorhofohrverschluss durch transperikardiale Ligatur
Intra-aortic balloon occlusion with extracorporeal circulation	Intraaortale Ballonokklusion mit extrakorporaler Zirkulation
Therapy of scoliosis using magnetically-controlled rods	Therapie der Skoliose mittels magnetisch-kontrollierter Stangen3
Direct acoustic stimulation of the cochlea by a Direct Acoustic Cochlear Implant (DACI)	Implantat zur direkten akustischen Stimulierung der Cochlea (DACI)

Procedure (English)	Procedure (German)
Apicoaortic valved conduit	Apikoaortales, klappentragendes Konduit
Insertion of covered stents with bioactive surface for peripheral and other vessels	Einlage beschichteter (gecoverter) Stents mit bioaktiver Oberfläche für periphere und andere Gefäße1
Minimally invasive LV repair with a myocardial anchoring system	Minimalinvasive LV-Rekonstruktion mit einem myokardialen Verankerungssystem
Selective intravascular radionuclide therapy (SIRT) with holmium 166-labeled microspheres for radioembolization	Selektive intravaskuläre Radionuklidtherapie (SIRT) mit Holmium- 166-markierten Mikrosphären zur Radioembolisation2
Insertion of covered stents with bioactive surface for intra-abdominal, cranial or peripheral vessels	Einlage beschichteter (gecoverter) Stents mit bioaktiver Oberfläche für intraabdominale, kraniale oder periphere Gefäße1
Implantation of grown heart valves	Implantation mitwachsender Herzklappen
Endovascular mitral valve annuloplasty with suture anchors	Endovaskuläre Mitralklappenanuloplastik mit Nahtverankerung
Epiretinal retinal prosthesis	Epiretinale Netzhautprothese
Insertion of covered stents with bioactive surface for visceral and supraaortic vessels	Einlage beschichteter (gecoverter) Stents mit bioaktiver Oberfläche für viszerale und supraaortale Gefäße1
Endovascular mitral valve annuloplasty	Endovaskuläre Mitralklappenanuloplastik
Fetoscopic drainage therapy	Fetoskopische Drainagetherapie
Telemetrically adjustable pulmonary artery banding	Pulmonalarterielles Banding, telemetrisch adjustierbar
Fetoscopic tracheal balloon occlusion for diaphragmatic hernia and premature rupture of the bladder	Fetoskopischer Tracheal-Ballonverschluss bei Zwerchfellhernie und bei vorzeitigem Blasensprung
Biologically coated keratoprosthesis	Keratoprothese, biologisch beschichtet
Scoliosis therapy by self-growing screw-rod system	Therapie der Skoliose mittels mitwachsendem Schrauben-Stab- System
Auditory brainstem implant	Auditorisches Hirnstammimplantat
Endo-Exo prosthesis	Endo-Exo-Prothese
Subretinal active implant	Subretinales aktives Implantat
Closure of umbilical cord and intrafetal vessels by means of percutaneous ultrasound-guided radiofrequency ablation or fetoscopic laser ablation	Verschluss von Nabelschnur- und intrafetalen Gefäßen mittels perkutaner ultraschallgesteuerter Radiofrequenzablation oder fetoskopischer Laserablation
Fetoscopic opening of narrowed semilunar valves and the foramen ovale	Fetoskopische Eröffnung von verengten Semilunarklappen und des Foramen ovale
Fetoscopic therapy of fetal supraventricular tachycardia and laryngeal or tracheal occlusion	Fetoskopische Therapie von fetaler supraventrikulärer Tachykardie und Kehlkopf- bzw. Luftröhrenverschluss
Implantation of an artificial larynx after total laryngectomy	Künstlicher Kehlkopf nach totaler Laryngektomie
Fetoscopic patch closure of human spina bifida aperta	Fetoskopischer Patchverschluss bei Spina bifida aperta

Procedure (English)	Procedure (German)
Uterine occluder system after fetoscopic surgery	Uterus-Schirmchenverschluss nach fetoskopischen Eingriffen
Growing endoprostheses	Wachstumsendoprothesen
Auditory midbrain implant	Auditorisches Mittelhirnimplantat
Simultaneous cochlear implantation and acoustic neuroma resection	Akustikusneurinomoperation mit gleichzeitiger Cochlea-Implantation4
Continuous amnioinfusion using a subcutaneously implanted port system	Kontinuierliche Amnioninfusion mittels subkutan implantiertem Portsystem
External stabilization structure for anastomosis of an AV shunt in the context of shunt surgery	Externes Stabilisierungsgerüst bei Anastomose eines AV-Shunts im Rahmen der Shuntchirurgie
Epiretinal retinal prosthesis with event-based camera	Epiretinale Netzhautprothese mit ereignisbasierter Kamera
Epiretinal retinal prosthesis or epiretinal retinal prosthesis with event-based camera	Epiretinale Netzhautprothese oder epiretinale Netzhautprothese mit ereignisbasierter Kamera
Transmission of virus-specific donor immune cells after allogeneic stem cell transplantation	Übertragung von virusspezifischen Spender-Immunzellen nach allogener Stammzelltransplantation2
Radionuclide therapy with Lutetium-177-labeled prostate-specific membrane antigen (PSMA) in prostate cancer	Radionuklidtherapie mit Lutetium-177-markiertem prostataspezifischen Membranantigen (PSMA) bei Prostatakarzinom2
Intracavitary radiotherapy with iodine-1252	Intrakavitäre Radiotherapie mit Jod-1252
Allogeneic hepatocyte transplantation	Allogene Hepatozytentransplantation2
Radioimmunotherapy with anti-CD19, anti-CD45 and anti-CD66 antibodies	Radioimmuntherapie mit Anti-CD19-, Anti-CD45- und Anti-CD66- Antikörper2
Autologous matrix-induced hepatocyte transplantation	Autologe matrixinduzierte Hepatozytentransplantation
Treatment of lethal epidermolysis bullosa junctionalis, Herlitz-type, by transplantation of haploidentical bone marrow and skin of the same donor	Behandlung der letalen Epidermolysis bullosa junctionalis (M. Herlitz) durch Transplantation von haploidentischem Knochenmark und Haut desselben Spenders
Combined kidney and stem cell transplantation (from a living donor)	Kombinierte Nieren- und Stammzelltransplantation (Lebendspende)
Radionuclide therapy with iodine-131-azetidinylamide in metastatic adrenocortical carcinoma	Radionuklidtherapie mit Jod-131-Azetidinylamid bei metastasiertem Nebennierenrindenkarzinom2
Radionuclide therapy with iodine-131-metomidate	Radionuklidtherapie mit Jod-131-Metomidat2
Radionuclide therapy with lutetium-177-bisphosphonate in bone metastases of prostate cancer	Radionuklidtherapie mit Lutetium-177-Bisphosphonat bei Knochenmetastasen des Prostatakarzinoms2
Uterus transplantation	Uterustransplantation
Full face transplantant	Vollständige Gesichtstransplantation

Break-down of selected technologies in 2016 by clinical area

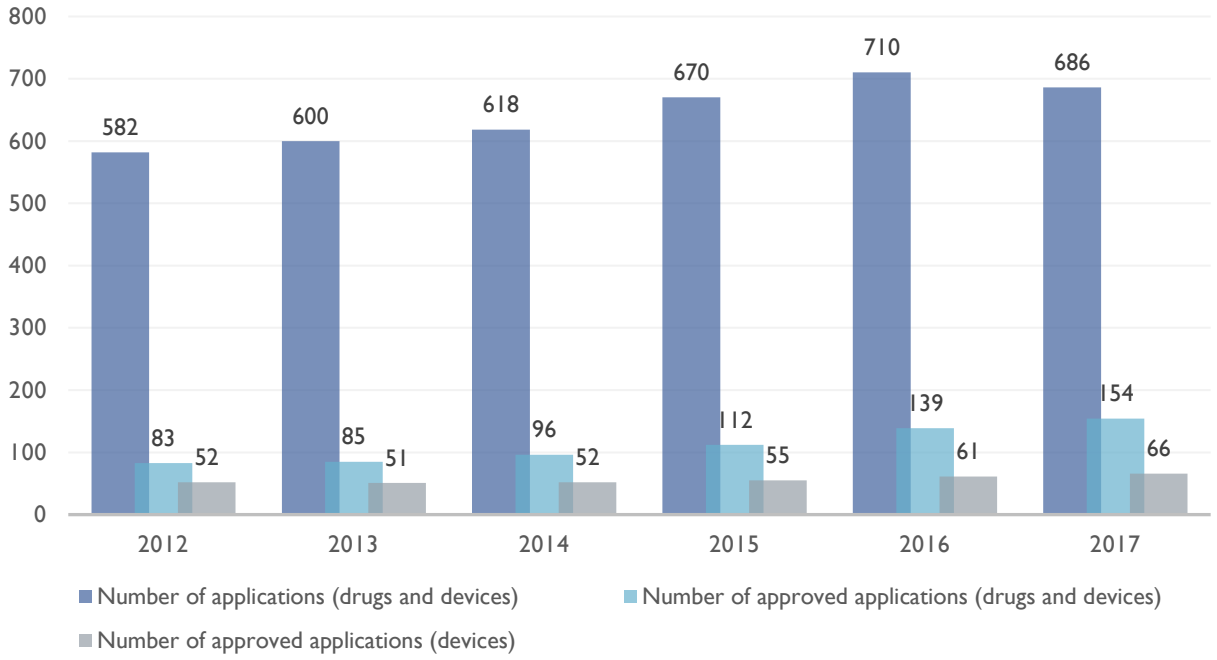
The table below shows the distribution of technologies that were selected in 2016 (for funding in 2017) by clinical area.

The most common technological areas were cardiovascular (27%), obstetrics and gynecology (14%) and nuclear medicine (9%).

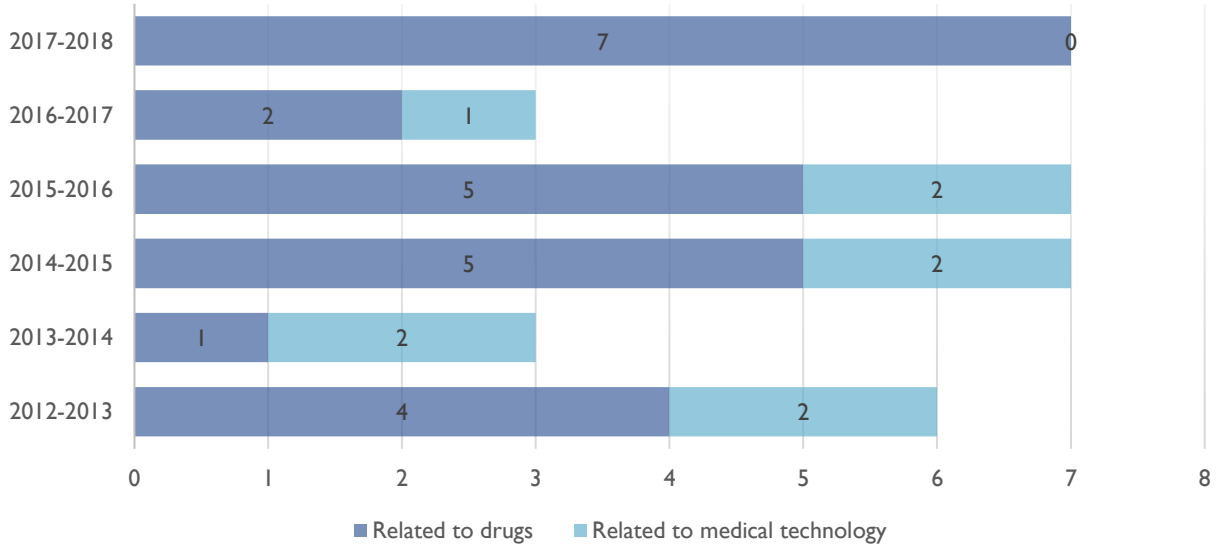
Technological area	Number	Percentage
Cardiovascular	18	27%
Obstetrics and gynecology	9	14%
Nuclear medicine	6	9%
Ear, nose, throat	5	8%
Ophthalmology	5	8%
Peripheral vascular	4	6%
Cell therapy	3	5%
Gastrointestinal	3	5%
Dermatology	2	3%
Neuromodulation	2	3%
Neurovascular	2	3%
Orthopedics	2	3%
Spine	2	3%
Dental	1	2%
Nephrology and urology	1	2%
Pulmonary and Airways	1	2%

Number of selected technologies from 2012 until 2017

The figure below shows the number of total applications for NUB innovation funding as well as the number of approved applications relevant for both drugs and devices, and for only devices, respectively.



The objective of NUB funding is 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 2017, a total of 34 NUB funded procedures were adapted. In total, 6 of them (18%) were integrated through the creation of novel DRGs and 28 (82%) were assigned an add-on payment (ZE). The figure below shows how many of the procedures that were integrated into the system in each year were related to drugs or medical technologies, respectively.



GERMANY: GOVERNMENT CO-FUNDED CLINICAL STUDIES (ERPROBUNGSSTUDIE)

Title

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

Objective

Co-funded studies were introduced in Germany in 2012 to provide the possibility of filling in missing evidence about the safety and efficacy of potentially beneficial methods for decision-making processes by the Federal Joint Committee (G-BA).

Overview

Co-funded studies in Germany are regulated in §137e of the Social Code Book V (SGB V). The framework applies to diagnostic or therapeutic methods that show a potential medical benefit, but for which available evidence is not sufficient to decide on inclusion as a benefit within statutory health insurance. Specific criteria described below define which methods are eligible for co-funded studies.

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

To directly apply for a co-funded study, manufacturers file an application form including a systematic literature review, outline of a suggested study and a letter of intent of cost-contribution. The G-BA then tests 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 calls hospitals that are using the method to provide additional information and then invites interested parties to make comments or suggestions.

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

Manufacturers can request a consultation by the G-BA to get guidance in the application process for a co-funded study at the cost of €500 to €10,000.

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

Funding

In cases where a co-funded study is induced through direct application by a manufacturer, the manufacturer must cover the main costs of the study, including administrative costs as well as costs for conduction and evaluation of the study. The amount depends on the scope (size and complexity) of the study and lies between €600,000 and €3,300,000, with a cost per patient of €1,500 to €9,000. Reduced contributions are required from small and mid-sized manufacturers (up to 50% less) and if rare diseases are concerned (additionally 20% less).

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

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. The amount of contribution is then determined in each case.

Inclusion criteria

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

- The method is expected to be less complex, less invasive or have fewer side effects than existing methods or to optimize 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 benefit in the outpatient catalog (EBM).

Applicant

Co-funded studies can be induced in different ways:

- Directly, through application by manufacturers (§ 137e (7) SGB V);
- Indirectly, in the process of a method evaluation by the G-BA
    - Early benefit assessment of high-risk devices 137h SGB V, which is requested by hospitals;
    - Introduction of a new procedure code into the outpatient catalog, EBM (§ 135 SGB V), which is requested by members of the G-BA;
    - Evaluation of a procedure in the inpatient sector (§ 137c SGB V), which is requested by members of the G-BA.

§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 organizations and can initiate method evaluations according to §§ 135 and 137c SGB V.

However, in these cases the G-BA will decide upon the induction of a co-funded study in order to create missing evidence to enable an evaluation process.

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 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, outline of 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 the 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 process of developing a study directive and considers scientifically valid suggestions.

Clinical and economic requirements for the scheme

As mentioned above, 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 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

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. Therefore, the full number of applications for co-funded studies in 2016 is unknown. It remains further unknown whether the reason for this was that the methods showed no potential benefit, that manufacturers were unwilling to contribute to costs, or that studies were already under way, making the creation of further evidence redundant.

Four directives for the conduction of co-funded studies were decided by the G-BA from the beginning of the regulation in 2012 to the present day. All of them are relevant only to the outpatient sector. The study guideline for one of the co-funded studies will come into effect with approval by the Federal Ministry of health within two months after a decision by the G-BA.

Procedure (English)	Procedure (German)	Decision	Effective	Initiation pathway
Magnetic resonance tomography-guided high-focussed ultrasound therapy for the treatment of uterine fibroid	Magnetresonanztomographie-gesteuerte hochfokussierte Ultraschalltherapie zur Behandlung des Uterusmyoms	15.12.2016	09.03.2017	137e (7), by Philipps and Insightec; outpatient sector
Stem cell transplantation in multiple myeloma	Stammzelltransplantation bei Multiplem Myelom	19.01.2017	13.04.2017	137c, by sickness funds; inpatient sector
Transcorneal electrostimulation in retinopathy pigmentosa	Transkornealen Elektrostimulation bei Retinopathia Pigmentosa	20.07.2017	07.10.2017	137e (7); outpatient sector
Measurement and monitoring of pulmonary artery pressure using an implanted sensor to optimize the therapy of NYHA III heart failure	Messung und Monitoring des pulmonalarteriellen Drucks mittels implantierten Sensors zur Therapieoptimierung bei NYHA III Herzinsuffizienz	19.10.2017	not yet effective	137e (7); outpatient sector

THE NETHERLANDS: CONDITIONAL FUNDING OF MEDICAL PROCEDURES

Title

Conditional funding of medical technologies within Basic Health Insurance (Voorwaardelijke toelating tot het basispakket).

Objective

The objective of the scheme is 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.

Overview

In the Netherlands, Basic Health Insurance is determined/guaranteed by the Health Insurance Law (Zorgverzekeringswet, Zvw). The Law describes care in very general terms, so there is a lack of clarity in many situations regarding what is covered. Dutch Health Care Institute (Zorginstituut Nederland) is responsible for determining the allocation of care under Basic Health Insurance (BHI). The position of the Institute is based on an assessment of clinical and economic evidence to determine conformity of care with "state of science and practice". Care is reviewed in according with criteria of necessity, effectiveness (conformity with "state of science and practice"), cost-effectiveness and feasibility (later – only in case of review before implementation of the method).

There are three ways of determining topics for assessment:

- Institute receives questions regarding whether or not care should be covered in the BHI from health insurers, health care providers, and patients. 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 creation of the procedure code (important way);
- In addition to responding to requests from different stakeholders, the Institute regularly reviews the care package (important way).

When the Institute does not establish conformity with "state of science and practice", the procedure is declined coverage within Basic Health Insurance. If care does not meet the criterion of "state of science and practice", but is promising, the Institute can open up the possibility of temporary, conditional reimbursement for a period of up to 4 years.

The pathway was established in January 2012. The pre-condition for submission is an available assessment from the Zorginstituut Nederland, which did not find the evidence sufficient to recommend technology for reimbursement within basic insurance package but mentioned the possibility of conditional reimbursement.

Applications for temporary reimbursement shall be made within three months after the release of the recommendation of the Institute about coverage of procedure within Basic Health Insurance.

Application triggers the complex 4-stage process of the selection of candidate technologies. The condition for temporary reimbursement is a collection of data about effectiveness and cost-effectiveness. During the period of reimbursement, a clinical trial shall be conducted in the Netherlands to bridge evidence gaps. The Institute and the Ministry of Health, Welfare and Sport make an annual decision about technologies, for which temporary reimbursement is provided.

When conditional reimbursement is activated, the cost of care will be covered by Basic Health Insurance. However, the cost of research itself shall be covered by private parties (e.g., manufacturer). After four years, the Dutch Health Care Institute reevaluates the service in scope and makes final recommendations about its inclusion into the Basic Health Insurance package.

Inclusion criteria

Selection criteria for services include the appropriateness of the intervention, the feasibility of research, social relevance and the promise of the service.

Applicant

There is no application for the program. Applicant (manufacturer) can 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 possibility to apply for temporary reimbursement Collects and reviews applications Advices Ministry of Health, Welfare and Sport and potential candidates for reimbursement Makes reevaluation of procedure after end of conditional period
Scientific Advisory Council (WAR)	Advise about selection of applicants
Dutch Organisation for Health Research and Development (ZonMw)	Hosts system for submission of dossiers Provides advice to the ZIN about quality of feasibility of research Provides subsidy for financing of research component
Ministry of Health, Welfare and Sport	Decision about awarding conditional reimbursement

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 about the scheme

Five technologies, including three medical technologies (60%), were selected for conditional reimbursement in 2018:

- Minimally invasive endoscopy-guided surgery with the Apollo system for the treatment of spontaneous, supratentorial, intracerebral hemorrhage;
- Extracorporeal shockwave therapy (ESWT) for the treatment of nonunions in the long bones;
- The use of the exoskeleton in patients with paraplegia.

Number of selected technologies for the last five years

Data about a total number of selected projects and selected projects related to medical technologies (including cell therapy) 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%)

THE NETHERLANDS: SMALL-SCALE EXPERIMENTS FOR THE INTRODUCTION OF INNOVATIONS

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 with the goal of improving the provision of care or making delivery of care more efficient. The scheme is considered a coverage with 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 projects concerning the ways of providing care (e.g., online consultation, telemonitoring, home neuromodulation, school counseling, 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 organizations;
- Improvement of quality of life of patients.

Provider(s) and the insurer(es) develop an agreement and send it to the Dutch Health Care Authority (NZa) for approval. NZa 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. The basic timeline of the project is three years with the potential to extend it up to 5 years. For other projects (under the Zorgverzekeringswet), there is no defined budget.

Inclusion criteria

The program covers the following topics:

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

Applicant

Provider and insurance company jointly develop the application.

Stakeholders involved

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

Clinical and economic requirements for the scheme

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

Statistics about the scheme

In 2017, six projects were approved, including only one related for medical devices (telemonitoring project) (17%).

Among 30 ongoing programs in February 2017, there were only six (20%) related to the provision of care involving medical technologies:

- Cardiotocography by obstetrics and midwives as an innovation in the first line of health care system;
- Mobile X-ray;
- Ambulatory lithium assay;
- Sleep apnea diagnosis in the first line of healthcare;
- Ambulatory neuromodulation;
- Telemonitoring by cardiology centers for patients at home.

Number of selected technologies for the last five years

A total number of projects approved annually (not specifically related to medical technologies) is presented in the table below.

Status	2013	2014	2015	2016	2017
Total number of approved projects	4	6	7	4	6

SWITZERLAND – PROVISIONAL REIMBURSEMENT OF MEDICAL PROCEDURES

Title

Provisional reimbursement of medical procedures (Leistungen in Evaluation).

Objective

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

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 services including devices and in-vivo diagnostics are covered by Swiss statutory health insurance (SHI) scheme without formal health technology assessments (HTA). However, in cases where there is doubt regarding the efficacy, appropriateness and efficiency of a medical service, the service can be challenged by anyone with a legitimate interest.

Potentially controversial medical services are reported to the Federal Office of Public Health (FOPH) who askes the provider or manufacturer to submit all available evidence on effectiveness, appropriateness, and cost-effectiveness of the method. The FOPH checks the completeness of evidence and compiles a dossier including a summary and indication of critical issues, which it passes on for an appraisal by the Federal Commission for Medical Benefits and Principles (ELGK). Based on the recommendation by the ELGK, the final decision is taken by the Federal Department of Home Affairs (EDI) in the form of one of three possible outcomes:

- Yes – continued coverage (with or without restrictions 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, centers 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).

Inclusion criteria

No specific inclusion criteria exist.

Applicant

Medical services can be contested by anyone with a legitimate interest. Typically, it is done by health insurance companies. Provisional reimbursement cannot directly be applied for; rather, it is one of three possible outcomes of the evaluation made by the Federal Department of Home Affairs (EDI).

Stakeholders involved

The following stakeholders are involved.

Stakeholder	Role
Health insurance company or another person with legitimate interest	Request for verification of eligibility of a medical service for coverage within statutory health insurance
Provider or manufacturer	Submission of available evidence about effectiveness, appropriateness, and cost-effectiveness of a method at request by the FOPH
Federal Office of Public Health (FOPH)	Collection of available evidence submitted by manufacturers or providers checks the completeness and summarizes in a dossier
Federal Commission for Medical Benefits and Principles (ELGK)	Appraisal of the evaluation dossier of a contested method by the FOPH
Federal Department of Home Affairs (EDI)	Makes final decision about coverage (yes; no; yes, in evaluation)

Clinical and economic requirements for the scheme

For a technology to be eligible for provisional reimbursement, all following questions besides 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 for 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 value and costs of conducting CED favorable?

7. Will the new evidence justify a potential change of the coverage decision?

More details about the requirements are provided in checklists for medical devices and diagnostic tests by the FOPH.

Statistics about the scheme

Only one technology was selected for the provisional reimbursement scheme in 2016. Information about the number of assessed technologies is not publicly available.

Currently (as for December 2017), there are eight technologies covered by provisional reimbursement:

Procedure (German)	Procedure (English)	Evaluation period
Autologe Chondrozytentransplantation zur Behandlung von posttraumatischen Knorpelläsionen am Kniegelenk.	Autologous chondrocyte transplantation for the treatment of post-traumatic cartilage lesions on the knee joint	1.1.2002/ 1.1.2004/ 1.1.2017 until 31.12.2019
Extrakorporelle Photopherese nach einer Lungentransplantation nur bei Bronchiolitis-obliterans-Syndrom, wenn augmentierte Immunsuppression sowie ein Behandlungsversuch mit Makroliden erfolglos waren.	Extracorporeal photopheresis after lung transplantation only in the case of bronchiolitis obliterans syndrome, when augmented immunosuppression and treatment with macrolides were unsuccessful	1.1.2009/ 1.8.2016 until 31.12.2019
Transkatheter Aortenklappenimplantation (TAVI) bei Patientinnen und Patienten mit schwerer Aortenstenose, die nicht operiert werden können oder ein hohes Operationsrisiko aufweisen	Transcatheter Aortic valve implantation (TAVI) in patients with severe aortic stenosis who cannot be operated on or who are at high risk for surgery	1.7.2013 until 30.6.2018
Fokussierte Ultraschalltherapie im Pallidum, Thalamus und Subthalamus zur Behandlung von: - Tremor bei etablierter Diagnose einer idiopathischen parkinsonschen Krankheit, Progredienz der Krankheitssymptome über mindestens 2 Jahre, Ungenügende Symptomkontrolle durch Dopamin-Behandlung (Off-Phänomen, On-/Off-Fluktuationen, On-Dyskinesien) - etablierter Diagnose eines nicht-parkinsonschen Tremors, Progredienz der Symptome über mindestens 2 Jahre, ungenügende Symptomkontrolle durch medikamentöse Behandlung - Behandlung schwerer chronischer therapieresistenter neuropathischer Schmerzen	Focused ultrasound therapy in the pallidum, thalamus and subthalamus for the treatment of: - Tremor in established diagnosis of idiopathic Parkinson's disease, progression of disease symptoms for at least two years, inadequate symptom control by dopamine treatment (off-phenomenon, on/off fluctuations, on-dyskinesia) - established diagnosis of non-Parkinsonian tremor, the progression of symptoms for at least two years, inadequate symptom control by drug treatment - Treatment of severe chronic refractory neuropathic pain	15.7.2015 until 30.6.2020

Procedure (German)	Procedure (English)	Evaluation period
Multigen-Test beim Mammakarzinom (Breast Cancer Assay) bei der indikation primäres, invasives Mammakarzinom mit folgenden Eigenschaften: - Der Östrogenrezeptor ist positiv. - Der humane, epidermale Wachstumsfaktor2-Rezeptor ist negativ (HER2-). - Bis zu 3 loko-regionale Lymphknoten sind befallen. - Konventionelle Befunde erlauben keine eindeutige adjuvante Chemotherapie-Entscheidung.	Multigenic Breast Cancer Assay for the indication primary, invasive breast carcinoma with the following characteristics: - The estrogen receptor is positive. - The human epidermal growth factor 2 receptor is negative (HER2-). - Up to 3 loco-regional lymph nodes are affected. - Conventional findings do not allow a clear adjuvant chemotherapy decision.	1.1.2011/ 1.1.2015 until 31.12.2018
Positron-Emissions- Tomographie (PET, PET/CT) bei der Fragestellung «Raumforderung», gemäss den klinischen Richtlinien der SGNM, Kapitel 2.0, vom 28. April 2011 zu FDG-PET.	Positron emission tomography (PET, PET / CT) in the question "Massaging", according to the clinical guidelines of the SGNM, chapter 2.0, dated April 28, 2011 on FDG-PET.	1.7.2014 until 31.12.2018
Positron-Emissions- Tomographie (PET, PET/CT) Mittels 18F-Fluorocholin bei folgender Indikation: Zur Abklärung bei biochemisch nachgewiesenem Rezidiv (PSA-Anstieg) eines Prostatakarzinoms	Positron emission tomography (PET, PET / CT) using 18F-fluorocholine with the following indication: To clarify biochemically proven recurrence (PSA increase) of a prostate carcinoma	1.7.2014 until 31.12.2018
Positron-Emissions- Tomographie (PET, PET/CT) Mittels Gallium-68-PSMA-11 bei folgender Indikation: Zur Abklärung bei biochemisch nachgewiesenem Rezidiv (PSA-Anstieg) eines Prostatakarzinoms	Positron Emission Tomography (PET, PET / CT) Using gallium-68-PSMA-11 with the following indication: To clarify biochemically proven recurrence (PSA increase) of a prostate carcinoma "	1.1.2017 until 31.12.2018

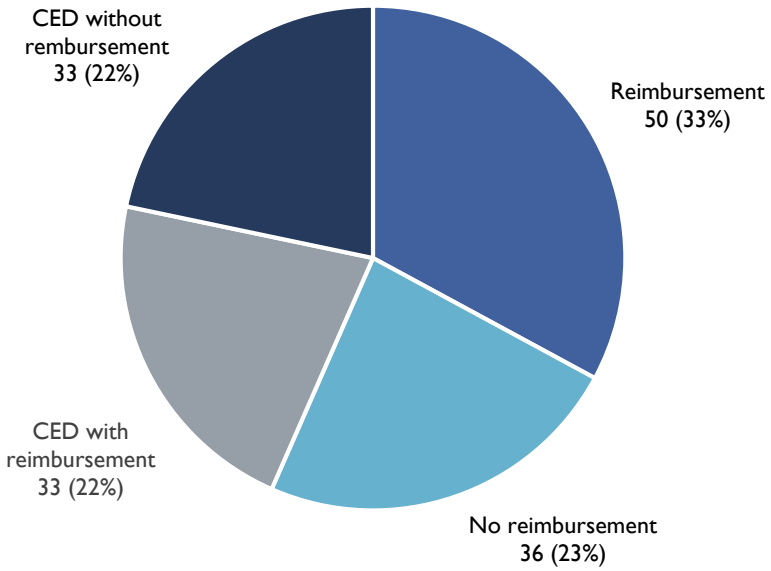
Note, that according to the feedback from the Federal Office of Public Health, certain stem cell transplantation procedures also belong to the provisional reimbursement scheme, although it is not specifically mentioned in the Annex 1 of the health care benefit ordinance (KLV).

Break-down of selected technologies by clinical area

Among eight currently covered technologies, the most common represent imaging methods (n=3; 38%).

Number of selected technologies for the last five years

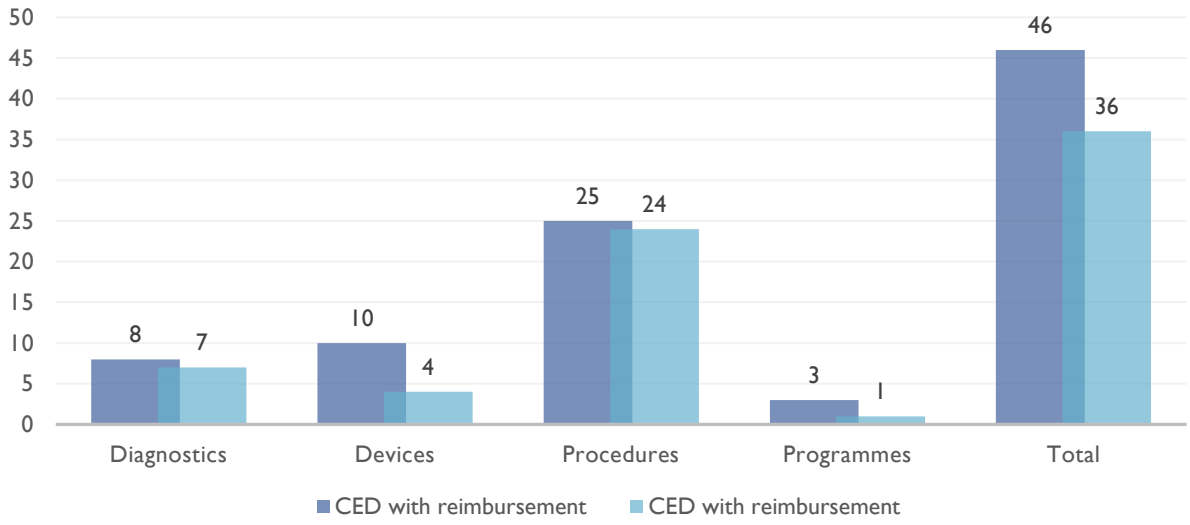
In an article published in 2015, Brügger et al.[1] analyzed the decisions made by the Federal Department of Home Affairs (EDI) in the context of evaluations of controversial medical services between 1996 and 2013. In total, 152 methods were tested during these years. For 50 (33%) of them, a direct decision for acceptance was made, 36 (23%) were not accepted for reimbursement, 33 (22%) of the methods received the status CED with reimbursement and 33 (22%) of the methods CED without reimbursement (see figure below). Note that the category "Evaluation without reimbursement" has been abandoned a while ago, because it did not have any practical meaning.



Methods that received the initial status CED are evaluated at least twice during the time and, therefore, several decisions were made. For the 152 contested medical services evaluated, a total of 234 decisions were made, and 82 (35%) of them were CED-decisions. The figure below shows the number of decisions for CED with and without reimbursement grouped by their type of medical technology as defined by the EuroScan database[2].

[1] Brugger, U., Horisberger, B., Ruckstuhl, A., Plessow, R., Eichler, K., & Gratwohl, A. (2015). Health technology assessment in Switzerland: a descriptive analysis of "Coverage with Evidence Development" decisions from 1996 to 2013. BMJ Open, 5(3), e007021-e007021. http://dx.doi.org/10.1136/bmjopen-2014-007021.

[2] Ibargoyen-Roteta N, Gutierrez-Ibarluzea I, Benguria-Arrate G, et al. Differences in the identification process for new and emerging health technologies: analysis of the EuroScan database. Int J Technol Assess Health Care 2009;25:367–73. (http://euroscan.org.uk/)



Analysis of the final reimbursement decisions for technologies that were selected for CED revealed that 59.4% of those with reimbursement and 42.9% of those without reimbursement during the evaluation period ultimately received a positive reimbursement decision.

On average, methods that were selected for CED with coverage remained in the evaluation status for 5.36 years until a final decision was made. The initial evaluation period was set at 4.3 years with an extension of 1.07 years. There was a high variation in the duration of evaluations from 0.5 to 11 years.