COCIR
Advancing Healthcare

LIVING REPOSITORY: MARKET ACCESS PATHWAYS FOR **DIGITAL HEALTH SOLUTIONS**

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

TABLE OF CONTENTS

1. INTRODUCTION

In recent years, Digital Health Solutions (DHS) have gained increasing momentum in healthcare delivery. This growing trend has prompted countries, both within and outside the EU, to pilot various market authorisation and access schemes. Some of these provide guidelines for coverage, while others provide clear pathways for reimbursement of DHS. *(38)*

Since 2020, COCIR has been investigating the status of DHS reimbursement in Europe and reporting on it in a compendium of country profiles that showcase developments in DHS reimbursement pathways. This series of reports is called Living Repository: Market Access Pathways for Digital Health Solutions.

Following our first edition in late 2020[1] and our collaboration with Synergus RWE for the second edition in late 2022, this is the third edition of the Living Repository: Market Access Pathways for Digital Health Solutions. The current edition has been prepared by the COCIR Office in collaboration with the COCIR National Trade Associations (NTAs). We would like to take this opportunity to express our special thanks to Agoria, and in particular to Mr Danny Van Rojen, for his support.

As in previous editions, this Compendium covers the same group of countries as the previous publications, namely:

- Belgium
- France
- Germany
- Spain
- Sweden
- United Kingdom

1 Market Access Pathways for Digital Health Solutions: https://www.cocir.org/media-centre/publications/article/market-access-pathways-for-digitalhealth-solutions.html

1.1. LIST OF KEY ABBREVIATIONS AND CONCEPTS

Beveridge healthcare system	A National Health Care System based on universal health care for all citizens, financed through taxation *(1)*.
Bismarck healthcare system	Also known as the "Social Health Insurance Model". The Bismarck model refers to government social insurance with prepayment by employees and their employers. It uses sickness funds as insurers to pay the doctor, hospital or other provider. The social insurance model is therefore based on compulsory coverage financed by both employers and employees *(1)*.
CED	Coverage with Evidence Development. A process where reimbursement is provided while additional evidence is generated. Typically, such a programme has a limited period of coverage.
DHS	Digital Health Solutions
EU	European Union
EUnetHTA – EUnetHTA21	European Network for Health Technology Assessment organisation
HTA – HTA-R	Health Technology Assessment – Health Technology Assessment Regulation 'A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system' *(2)*. On 15 December 2021, Regulation (EU) 2021/2282 of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU was published *(2)*.
MDD	Medical Device Directive *(3)*
MDR	Medical Device Regulation *(4)*
NICE	National Institute for Health and Care Excellence UK organisation that provides national guidance and advice to improve health and social care. This includes carrying out HTA evaluations of drugs, medical devices and diagnostics. NICE has developed a framework for the evaluation of Digital Health Solutions, but in practice this is not linked to a specific evaluation programme.
NTAs	National Trade Associations
Pathway	For the purposes of this report, a pathway is defined as a structured process leading to a decision that enables a recommendation, policy and/or coverage.
QALY	Quality Adjusted Life Year
RCT	Randomized Clinical Trial
RWE	Real World Evidence

2. DIGITAL HEALTH SOLUTIONS: THE FRAMEWORK

The three (3) levels of market access for digital health solutions are: [i] market authorisation, i.e. CE marking, [ii] Health Technology Assessment and [iii] coverage, i.e. pricing, procurement and reimbursement.

To better understand the progress of reimbursement of DHS in Europe, we examine how national healthcare models affect the development of reimbursement pathways under the existing regulatory framework, which includes CE marking, HTA, privacy and (cyber) security considerations.

2.1. HEALTHCARE MODELS AND MARKET ACCESS PATHWAYS

European national healthcare systems follow a variety of organisational and financing models. This diversification is reflected in the reimbursement pathways for Digital Health Solutions.

More specifically, in the Beveridge countries, it is the budget holders who decide on the reimbursement of DHS. An illustrative example is the UK, where the National Institute for Health and Care Excellence (NICE) is charged with making recommendations on the value of DHS but does not have the authority to make decisions on their reimbursement. This power lies with the Integrated Care Boards*(5)*, which are responsible for budgeting and commissioning. In other words, in the UK, a positive recommendation at national level is not sufficient; additional steps at local level would be required to lead to reimbursement. Consequently, the existence of pathways in Beveridge-type countries (Table 1) is not directly linked to reimbursement.
Conversely, in the Bismarck countries*(1)*Social Security health models apply; this tends to link Digital Health Solutions pathways directly to a decision on reimbursement. (Table 1)

NO REIMBURSEMENT PATHWAY FOR DIGITAL HEALTH (Beveridge)	**REIMBURSEMENT PATHWAY FOR DIGITAL HEALTH (Bismarck)**
Spain Sweden United Kingdom	Belgium France Germany

Table 1 *Types of healthcare systems.*

Table 2 below also illustrates the link between market access pathways - as developed under the different health care models - and their impact on DHS reimbursement.

MARKET ACCESS PATHWAY (COUNTRY)	**OUTCOME**	**IMPACT ON REIMBURSEMENT**
Evidence standards framework for digital health solutions (UK/Beveridge) *(6)*	Guidance to DHS developers regarding methodological considerations.	No direct link to uptake or reimbursement.
Application process for mobile medical applications (BE/Bismarck) *(7)*	Temporary (conditional) or permanent reimbursement.	Direct link to reimbursement.
Digital Health Application Regulation (DiGA) (DE/Bismarck) *(8)*	Either conditional reimbursement for one year while evidence is generated. OR Reimbursement	Direct link to reimbursement

Table 2 *Examples of pathway outcomes and impact*

2.2. DIGITAL HEALTH SOLUTIONS: SCOPE AND CLASSIFICATION

Digital Health Solutions refer to a wide range of technologies and applications aimed at supporting the delivery of healthcare - both stand-alone and integrated into medical devices and diagnostics *(38)*. Examples of DHS include telemedicine, mobile health applications, health data analytics and digital therapeutics, or even electronic health records. DHS can support web-based consultations with health professionals, remote patient monitoring, real-time updating of algorithms based on patient data, or even the delivery of health interventions.

In this context, the market access pathways for DHS identify the eligible types of DHS and the eligibility criteria for their potential reimbursement - in terms of regulatory compliance and functional scope, i.e. the type of support that DHS are intended to provide. In other words, typical requirements in a reimbursement pathway for DHS include regulatory restrictions - i.e. CE marking and, occasionally, the regulatory classification of the DHS according to the MDR *(4)* - combined with the functional scope of the DHS.

For example, in Belgium, in order for a DHS to be eligible for reimbursement, it must be CE marked, but without specific limitation to its classification according to the MDR. It must also comply with the functional scope of allowing "a healthcare professional to diagnose, administer therapy or monitor a patient remotely via a medical device intended for use by the patient in his/her own environment". In Germany, on the other hand, the DiGA process is more patient-centric, making this patient-centricity a key criterion for reimbursement. Overall, Digital Health Solutions with therapeutic outcomes, but without regulatory classification limitations, tend to offer broader scope.

In conclusion, even if a DHS is legally compliant, it may not be reimbursable in a particular EU Member State. This is because each national system has its own focus in terms of how it supports patients or clinicians - e.g. Belgium requires integration into the care pathway, whereas Germany takes a more direct2patient approach.

Table 3 below examines the reimbursement pathways of DHS in 3 EU Member States in combination with the functional scope.

DHS FUNCTIONAL SCOPE	**REIMBURSEMENT PATHWAY FOR DIGITAL HEALTH (Bismarck)**		
This comparison aims to capture the functional scope of the different market access pathways. By combining the functional scope with the limitations imposed by regulatory classification, it is possible to distil a narrative definition.	BELGIUM	GERMANY	FRANCE
REMOTE MONITORING	X		X
DHS WITH THERAPEUTIC BENEFIT			X
PATIENT DHS LINKED TO ACTION BY HEALTHCARE PROFESSIONAL			
DHS CENTRED AROUND PATIENT		X	
DIGITAL ASSISTANTS IN LONG-TERM CARE		X	

Table 3 *Compared scope of Digital Health Solutions included in 3 EU Member States.*

2.3. DIGITAL HEALTH SOLUTIONS AND MARKET AUTHORISATION

The EU Regulation on Medical Devices (MDR) *(4)* represents a significant improvement in the overall safety, performance and clinical evaluation process for Digital Health Solutions. However, not all Digital Health Solutions currently allowed on the market have undergone the same evaluation process *(39)*, as some have already been authorised under the MDR's predecessor, the EU's Medical Devices Directive (MDD) *(3)*.

DHS REGULATORY CLASSIFICATION	REIMBURSEMENT PATHWAY FOR DIGITAL HEALTH (Bismarck)		
	BELGIUM	GERMANY	FRANCE
The MDR has brought about a significant change in the classification of Digital Medical Devices, putting them on an equal footing with traditional devices: **MDCG 2023-4** Medical Device Software (MDSW) -- Hardware combinations; Guidance on MDSW intended to work in combination with hardware or hardware components (October 2023) **MDCG 2019-11** Guidance on Qualification and Classification of Software in Regulation **(EU) 2017/745 - MDR** and Regulation **(EU) 2017/746 – IVDR** * *Germany plans to extend the scope of the Digital-Gesetz to Class IIb. This is currently in the legislative process with 1st reading in the Bundesrat on 20 October 2023 (40)*			
I	X	X	X
IIa	X	X	X
IIb	X	(X)*	X
III			X

Table 4 *Comparing Digital Health Solutions scope based on regulatory classification in 3 EU member states.*

2.4. DIGITAL HEALTH SOLUTIONS: PRIVACY AND SECURITY

Digital Health Solutions (DHS) are placed on the market to inform patients about their physical condition and to transmit this information to specific healthcare professionals and settings. Prior to the EU's Medical Devices Regulation (MDR), Digital Medical Devices were approved under the EU's Medical Devices Directive (MDD). In this context, many countries required additional safety requirements, such as independent testing at national level, to address risks related to cybersecurity, data protection and interoperability. The MDR together with its implementing acts and guidance *(9)*, can now mitigate such risks.

2.5. DIGITAL HEALTH SOLUTIONS AND HEALTH TECHNOLOGY ASSESSMENT

Every day, new Digital Health Solutions (DHS) emerge, promising to optimise healthcare delivery. To assess their benefits, efficiency and value, many countries have developed dedicated processes. National Health Technology Assessment (HTA) *(2)* bodies scrutinise the benefits and value of Digital Health Solutions, contributing to informed policy decisions, including on coverage - i.e. pricing, procurement and reimbursement.

In short, HTA examines the value of a new DHS by comparing its level of performance to the current standard of care and determining its cost-effectiveness. Based on the HTA results, the competent authority can then decide on the possible coverage of this DHS. (see Figure 1).

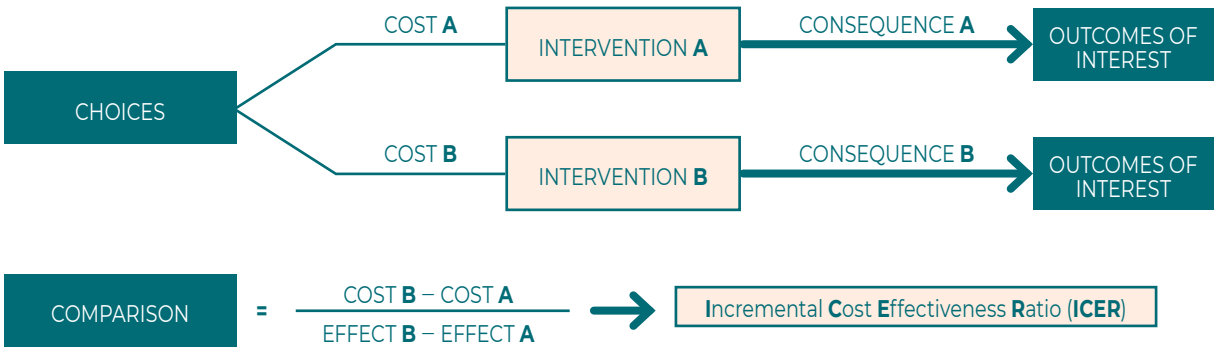

Figure 1 *Cost effectiveness methodology.*

In principle, HTA for Digital Health Solutions targets the improved outcome of interest, the economic consequences, or the combined measure of cost-effectiveness. To standardise the comparison between different therapeutic areas, the preferred outcome of interest is expressed in Quality-Adjusted Life Years (QALYs) and measured with standardised instruments, such as the Euroqol EQ-5D *(10)* or the SF-36 *(11)*.

Traditionally, the methodological evaluation frameworks include three (3) categories of clinical endpoints: Mortality, Morbidity and Health Related Quality of Life *(12)*. However, recognising the limitations of the traditional categories, the German DiGA process introduced new outcome categories such as adherence, improved adherence to guidelines and expectation of medical benefitsb *(13)*. Following the German example, other countries have also introduced new categories, such as the outcome of improved efficiency.

Overall, to assess the organisational benefits (value) of DHS, national pathways tend to compare the resources required before and after DHS implementation. An illustrative example is France and its targeted guidance on how to capture this type of organisational benefit *(14)*. Table 5 below provides a comparison between the value and benefit categories as defined in different countries.

VALUE / BENEFIT	VALUE / BENEFIT CATEGORIES		
	BELGIUM	GERMANY	FRANCE
Traditionally, HTA evaluations have focused on reducing mortality/morbidity and improving quality of life, as well as health economic impact. These outcomes are still essential for assessing value.			
Mortality, Morbidity, Quality of Life	X	X	X
New ways of assessing the value of DHS exist, but there is limited experience of translating them into reimbursement decisions.			
Organisational improvements	(X)	(X)	X
Health Economics	X		
(The comparison and categorization are simplified and do not cover all aspects.)			
Novel patient centric outcomes		X	

Table 5 *Comparing value and benefit utilized in 3 EU member states.*

The provision of evidence is crucial to any evaluation process, including HTA. For drugs, for example, HTA focuses on efficacy trials with high internal validity *(16)* – because their mode of action is based on a biological effect, with limited consideration of the context in which the trial was conducted. In contrast, the desired outcome of DHS is a change, i.e. a change in patient behaviour or a change in healthcare delivery.
In conclusion, while HTA of medicinal products can safely focus on Randomised Clinical Trials (RCTs), this is not the case for Digital Health Solutions. Here, RCTs are not always the best option to provide a true efficacy result *(15)*. On the other hand, Real-World Evidence (RWE) *(17)* could provide results with high external validity *(16)*. Finally, at the European level, the European Regulation on Health Technology Assessment *(2)* aims to facilitate the HTA process and avoid duplication of effort through a common HTA framework with streamlined methods and criteria. Overall, as a lengthy process, would HTA for DHS promote the uptake of innovation in EU Member States? It would most likely delay it.

2.6. EVALUATION OF EVIDENCE FOR DHS COVERAGE

Recognising the need to support innovation, some DHS pathways opt for the Coverage-with-Evidence-Development (CED) approach, where only an initial level of evidence is required for Digital Health Solutions to enter the market. This initial requirement is followed by an additional requirement to provide more conclusive evidence after a defined period of time.

Table 6 provides an overview of the evidence requirements in Belgium, Germany, and France for reimbursement of DHS. Overall, where a pathway includes more than one coverage decision, as is the case for Coverage with Evidence Development, these are treated as separate pathways to illustrate the difference between the two stages.

EVIDENCE REQUIREMENTS
Randomised Clinical Trials (RCTs) are still considered the gold standard for HTA evaluations. However, countries start considering other options for the provision of evidence that go beyond RCT, including well- designed Real-World Evidence (RWE) studies.

EVIDENCE REQUIREMENTS			
	BELGIUM	GERMANY	FRANCE
RCT	X	X	X
Non-RCT studies	(X)	(X)	(X)
RWE	(X)	(X)	(X)

Table 6 -*Comparison of evidence requirements in 3 EU Member States.*

2.7. ECONOMIC EVALUATION FOR DHS COVERAGE

Economic evaluation is a tool to identify, measure and compare the costs and outcomes of different Digital Health Solutions - in the sense of public health interventions, be they policies or programmes (c.f. Figure 1). Economic evaluation can simultaneously consider the resources used and the health outcomes achieved. It is an important tool to support decision making, especially when resources are limited.

There are four (4) types of economic evaluation: economic impact analysis, programme cost analysis, benefit-cost analysis and cost-effectiveness analysis. All these different methods can be used to evaluate the economic consequences of introducing new Digital Health Solutions.

Belgium is currently the only country that uses both economic impact and cost-effectiveness analyses to evaluate Digital Health Solutions.

3. COUNTRY-REPORTS

3.1. BELGIUM

The mHealth validation pyramid (see Figure 2) was introduced in 2018. Initially, the assessment focused on whether the software/mobile application was CE-marked as a medical device (level 1 or M1) and whether it could ensure interoperability and secure connectivity (level 2 or M2) *(7)*. It should be noted that the assessment of the M1 and M2 level criteria was not linked to reimbursement.

However, at the beginning of 2021 *(18)*, the third level criteria (M3) were published and these led to conditional DHS reimbursement. The third level criteria (M3) required the demonstration of socio-economic added value, which led to the conditional reimbursement of the first DHS in April 2022 *(19)*.
In summary, in Belgium, a mobile medical application that had completed both levels M1 and M2 and met the third level criteria (M3) within a specific care process could be reimbursed, either temporarily or permanently. Interestingly, in Belgium, reimbursement does not apply to the DHS per se, but rather to its utility for the care pathway. In other words, the decision to reimburse a DHS is based on the review of an entire care pathway.

Figure 2 *mHealth pyramid.*

From 1 October 2023, a new procedure applies in Belgium. The above-mentioned tiered approach is now obsolete. However, the former requirements of the M1-M2-M3 levels are maintained and integrated into a single procedure. The application for reimbursement must be submitted to RIZIV-INAMI.

The main changes of the new procedure are as follows:

- Registration on the mHealth Belgium portal is no longer required
- Applications used exclusively in hospital ecosystems are not eligible for reimbursement
- Smartphone applications are not the only type of digital health solution eligible for reimbursement
- Reimbursement covers the use of the mHealth app as part of the care pathway, not the application itself
- Different types of actors - i.e. companies, scientific associations, professional organisations and hospitals - can submit a request for temporary or final reimbursement by RIZIV-INAMI.

  This request is followed by a specific process of [i] assessing the eligibility of the criteria, [ii] drafting the assessment report and [iii] drafting a reimbursement proposal in case of a positive assessment.

  In the event of a recommendation for reimbursement, a transitional reimbursement scheme may be put in place pending the review of the care pathway. This review is necessary because, as with the pyramid, the new approach aims to reimburse the benefit that the DHS brings to the specific care pathway, rather than the DHS per se. Therefore, a review of the care pathway is required before a DHS can be reimbursed on a permanent basis.

COVERAGE WITH EVIDENCE DEVELOPMENT

Under the new procedure, there is an option to apply for early access. This means that in the case of innovative technologies with partially proven evidence of technological value, a temporary reimbursement could apply while additional evidence is gathered by the applicant to address existing knowledge gaps or uncertainties in the use of the technology. The new Belgian process aims to scientifically assess the added value of the DHS, involving all relevant stakeholders.

COUNTRY PROFILE (REGION optional)	**BELGIUM**	
SCOPE	☑ Medical devices (CE Mark)	☐ Other
REIMBURSEMENT	☑ Statutory Health Insurance	☑ Private insurance
REIMBURSEMENT (additional)	Reimbursement	Reimbursement by specific insurers
DHS - TYPE	mHealth applications	
DHS - DEFINITION / DESCRIPTION	A CE-marked medical device that allows a patient to share health-related information (with or without sensors) from their own environment with a healthcare professional, and for a healthcare professional to diagnose, treat or monitor a patient remotely via a medical device made for use by the patient in their own environment.	
LEGAL FRAMEWORK	Not based on specific legislation.	
INVOLVED AUTHORITIES	• RIZIV/INAMI (the National Institute for Health and Disability Insurance - NIHDI) • eHealth platform	
ASSESSMENT DOMAINS	• Technical: cloud storage, data transfers, operating systems, certificates • Scientific: population, care pathway, mHealth integration, scientific analysis • Economic: cost elements, budget impact analysis, health economic data • Literature study & Reference list	
PROCESS	Companies, scientific associations, professional organisations and hospitals can submit a request for temporary or definitive reimbursement to RIZIV-INAMI. • Firstly, RIZIV-INAMI will check that the application is admissible. (indicative timeframe 30 days) • Once accepted, the application will be evaluated by a permanent multi-stakeholder group, with the support of some ad hoc experts depending on the pathology and care pathway. (indicative timeframe 120 days) • After a positive evaluation, the relevant stakeholders within RIZIV-INAMI will discuss the revision of the care pathway. (indicative timeframe 150 days) • The revised care pathway needs to be validated and approved by the relevant committees within RIZIV-INAMI. (indicative timeframe 90 days) • As a final step, reimbursement needs to be formalised, either in the form of an agreement or a Royal Decree. (indicative timeframe 60 or 180 days) A more detailed flow chart of the process is available on the RIZIV-INAMI website. • Dutch - https://www.riziv.fgov.be/SiteCollectionDocuments/schema_procedure.pdf • French - https://www.riziv.fgov.be/SiteCollectionDocuments/schematique_procedure.pdf	

COUNTRY PROFILE (REGION optional)	BELGIUM	
Criteria on Value Based Care	From the INAMI notification form *(20)*: • Relevance to the target population • Impact of the product on the care pathway • Comparative effectiveness in terms of quality of care or quality of life for the patient. • Budgetary impact • Cost-effectiveness NB. Foreign studies require further justification as to their applicability in the Belgian setting	
ACCEPTANCE OF CLINICAL DATA	☑ Data from populations outside the local market	☐ Data from a similar device
RELEVANT COCIR NTA	Agoria	www.agoria.be/en
REFERENCES	mhealth Belgium	

3.2. FRANCE

France has run several pilot programmes in the past to evaluate different reimbursement models for DHS. These pilots led to a more permanent model for the reimbursement of Digital Health Solutions for remote monitoring. Indeed, the new regulation published at the beginning of 2023 outlines these new pathways and withdraws all the previous - temporary - ones.

REMOTE MONITORING (LATM)

Since 2009, the previous programme (ETAPES) introduced several pilot projects to reimburse remote monitoring solutions. The scope of these solutions was limited to remote monitoring without a clear therapeutic effect. These pilots led to the development of a "liste des activités de télésurveillance médicale" (LATM) *(21)*, a new permanent pathway for remote monitoring solutions. The corresponding regulation was published on 30 December 2022 *(22)*.

As a first step, the LATM pathway will continue to cover the five clinical indications previously included in ETAPES:

- cardiac implants
- chronic obstructive pulmonary disease (COPD)
- diabetes
- heart failure
- renal failure

This is because France has developed a list of criteria for evaluating DHS for these five (5) diseases so that they can be reimbursed according to a single tariff per category.

New disease areas could be introduced at the request of companies wishing to register a specific product or brand. An individual tariff will be set for the first products in a new category. When there are sufficient products within a given category, a generic performance specification can be established, resulting in a single tariff per category.

A first telemonitoring solution for oncology called RESILIENCE *(41)* has been listed for LATM reimbursement.

THERAPEUTIC DIGITAL HEALTH SOLUTIONS (LPPR)

Digital Health Solutions with a therapeutic or diagnostic purpose can be registered in the Register of Reimbursable Products and Services (LPPR) *(23)*.
As a reminder, Digital Health Solutions are considered "medical aids" according to Title 1 of the LPPR legislation *(23)*, and therefore follow the same evaluation process as traditional medical devices -that is, through well-designed randomised clinical trials (RCT) that aim to demonstrate a meaningful effect, i.e. reduced mortality, morbidity, disability or improved quality of life.
Occasionally, France may accept non-randomised data, particularly when it is not possible to carry out an RCT or when a novel therapy can provide a clear signal of the DHS effect.

COVERAGE WITH EVIDENCE DEVELOPMENT

Inspired by the German fast-track reimbursement approach (DiGA), France has introduced a new a pathway called Prise en charge anticipée (PECAN). This new pathway can provide Coverage with Evidence Development *(24)*, i.e. conditional DHS reimbursement for a certain period of time during which the technology developer would work on the required evidence. The timeframe is defined as nine (9) months for products on the LATM list *(24)* and 6 + 6 months for products on the LPPR list. *(24)*.

COUNTRY PROFILE (REGION optional)	FRANCE	
SCOPE	☑ Medical devices (CE Mark)	☐ Other
REIMBURSEMENT	☑ Statutory Health Insurance	☑ Private insurance
REIMBURSEMENT (additional)		
DHS – TYPE	**PECAN** *(**P**rise **e**n **c**harge **an**ticipée):* Products reimbursed via LATM (without specification) or LPPR **LATM** *(**L**iste des **a**ctivités de **t**élésurveillance **m**édicale):* Remote monitoring **LPPR** *(**L**iste des **P**roduits et **P**restations **R**emboursables* prévue à l'article L. 165-1 du Code de la sécurité sociale): any DHS that can demonstrate a therapeutic effect	
DHS - DEFINITION / DESCRIPTION	**PECAN:** Products with a potential benefit, but for which there is not yet sufficient evidence to qualify for LATM or LPPR registration **LATM:** Remote monitoring solution **LPPR:** Solutions with therapeutic benefit	
LEGAL FRAMEWORK	**PECAN:** https://has-sante.fr/upload/docs/application/pdf/2023-03/pecan_guide_de_depot_de_dossier.pdf **LATM:** https://www.legifrance.gouv.fr/codes/article_lc/LEGIAR TI000044565986/2022-09-01 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000046849110 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000046849231 **LPPR:** https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006073189/ LEGISCTA000006172525/#LEGISCTA000006172525	
INVOLVED AUTHORITIES	Haute Autorité de Santé (HAS) Comité Économique des Produits de Santé (CEPS)	
ASSESSMENT DOMAINS	**All pathways:** Cybersecurity **LATM:** A specific list of requirements is being developed for defined product categories. **LPPR** *(25)*: • Product benefit • Public health benefit	
PROCESS	**All pathways** require the product to undergo a separate cybersecurity assessment. **PECAN:** • The developer submits a simplified dossier to claim compensation for a period of 6-12 months while the necessary evidence is gathered. • This payment is less than the expected permanent reimbursement • At the end of this period, a full dossier is submitted for the relevant LATM / LPPR process. **LATM:** • For products with an existing specification, a simplified registration is required to demonstrate that the product meets these requirements. • For products without a specification, a more comprehensive assessment is carried out. **LPPR:** • The developer submits a dossier to the HAS. The assessment focuses on the clinical added value of the DHS. • The subsequent negotiation with CEPS on the reimbursement tariff for the product is based on the results of this assessment.	

COUNTRY PROFILE (REGION optional)	**FRANCE**	
CRITERIA ON VALUE BASED CARE	**LATM**: • No criteria relevant to value-based care **LPPR**: • Traditional outcomes, such as mortality, morbidity, and quality of life • Organisational improvements	
ACCEPTANCE OF CLINICAL DATA	☑ Data from populations outside the local market	☐ Data from a similar device
RELEVANT COCIR NTA	Snitem	www.snitem.fr
REFERENCES	Provided in the "Legal Framework"- segment of this Country Fiche.	

3.3. GERMANY

Germany has been at the forefront of establishing a reimbursement pathway for Digital Health Solutions. This pathway, called DiGA, was launched in September 2021 and has attracted the interest of Digital Health Solutions developers. By January 2023, 37 DHS products had been added to the DiGA list *(42)*, either temporarily or permanently.

According to the latest report by SVDGV-Spitzenverband Digitale Gesundheitsversorgung – a national association representing eHealth providers in Germany – digital health applications "on prescription" are firmly anchored in the German healthcare system. The DiGA-Report by SVDGV *(43)* is entitled *Marktentwicklung digitaler Gesundheitsanwendungen* and covers the period between 01 Oktober 2020 and 30 September 2023. The report highlights that since autumn 2020 more than 370,000 unlock codes for digital health apps have been redeemed – astonishingly half of them in the last year alone. This dynamic growth is described as 215% in the 1st year, 65% in the 2nd year, and as an average monthly growth rate of 19% over 36 months. The SVDGV report also underlines the scientific evidence factor – with DiGA manufacturers having conducted randomized clinical trials far beyond the legal requirements.

Before that, the National Association of Statutory Health Insurance Funds (GKV) *(26)* conducted a review of the DiGA pathway. It recognised the potential of Digital Health Solutions, while highlighting specific limitations in their evaluation and reimbursement *(26)*. According to this report, the total revenue from the use of DiGAs amounted to €55 million in 2022. DiGAs were targeted at patient groups of different sizes - from 10 to 12,000 patients. During the temporary reimbursement period, DiGA reimbursement rates ranged from €119 to €952 for a 90-day period.

In addition to the DiGAs, a new pathway called DiPA was established *(27)* in 2022. DiPA targets Digital Health Solutions for patients in long-term home care. This pathway is similar to DiGA, except that DiPA does not provide coverage with evidence development and therefore conditional reimbursement during the evidence development period.

COUNTRY PROFILE (REGION OPTIONAL)	**GERMANY**	
SCOPE	☑ Medical devices (CE Mark)	☐ Other
REIMBURSEMENT	☑ Statutory Health Insurance	☐ Private insurance Varies between insurers.
REIMBURSEMENT (additional)	**DiGA:** All insured (73 million) **DIPA:** Those covered by the social long-term care health insurance (4 million)	
DHS - TYPE	**DiGA:** Intended use focused on the patient, possibly including the attending physician, and where the main function relies on the digital solution. **DiPA:** "Digital assistants" that can be used by care recipients or in the interaction of care recipients with relatives, other voluntary carers or outpatient care facilities *(28)*.	

COUNTRY PROFILE (REGION OPTIONAL)	GERMANY
DHS - DEFINITION / DESCRIPTION	**DiGA** *(8)* • Medical device of MDR risk classes I, IIa – and IIb, when the Digital-Gesetz is finally adopted – or, within the scope of the transitional provisions of the MDR, according to the Medical Device Directive (MDD). • The main function of DiGA is based on digital technologies. • DiGA is not a digital application that merely reads or controls a device; the medical purpose must be substantially achieved by the main digital function. • The DiGA assists in the detection, monitoring, treatment, or mitigation of disease or the detection, treatment, mitigation, or compensation for injury or disability. • DiGA is not used for primary prevention (see also chapter 2.1.4 DiGA for prevention). • The DiGA is used jointly by the patient or by the healthcare provider and the patient, i.e. applications that are only used by the doctor to treat patients ("practice equipment") are not DiGA. • The DiGA does not contain any services that are excluded according to the Third Chapter of the German Social Security Code, Book V, or for which the Federal Joint Committee has already made a negative decision according to §§ 92, 135 or 137c. **DiPA** *(29)* • The functionality of the product replaces a medical device under the MDR; CE marking is required. • Products outside the scope of a medical device may also be included. • A DiPA is mainly based on digital technologies (software). • The DiPA list can include devices, sensors, or other hardware as long as the main function is predominantly digital. • The nursing benefit is achieved through the DiPA and (if applicable) the additional support services required for the DiPA. The DiPA is not a digital application that merely reads or controls a device. • A DiPA is used to reduce impairments to the independence or capabilities of the person in need of care, or to counteract an increase in the need for care, and thus to provide a nursing benefit. • A DiPA can be used by care recipients alone or by care recipients in interaction with family members, other voluntary carers and licensed care or support services. • A DiPA can also support family carers or other voluntary carers in caring for the person in need of care or in managing the household. However, the prerequisite is that the DiPA serves to stabilise the care situation of the person in need of care at home. • A DiPA is designed to support the person in need of care exclusively in a domestic context.
LEGAL FRAMEWORK	**DiGA** • German Ministry of Health: Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG) (30 August 2023). *(40)* • Erste Verordnung Zur Änderung Der Digitale Gesundheitsanwendungen-Verordnung." Bundesgesetzblatt Teil I, no. 67 (September 24, 2021): 4355. • "Gesetz Für Eine Bessere Versorgung Durch Digitalisierung Und Innovation (Digitale-Versorgung-Gesetz – DVG)." Bundesgesetzblatt Teil I, no. 49 (December 18, 2019): 2562. • "Gesetz Zur Digitalen Modernisierung von Versorgung Und Pflege (Digitale-Versorgung- Und-Pflege-Modernisierungs-Gesetz – DVPMG)." Bundesgesetzblatt Teil I, no. 28 (June 8, 2021): 1309. • "Verordnung über das Verfahren und Die Anforderungen zur Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der Gesetzlichen Krankenversicherung (Digitale Gesundheitsanwendungen-Verordnung – DiGAV)." Bundesgesetzblatt Teil I, no. 18 (April 20, 2020): 768. **DiPA** • "Verordnung über das Verfahren und Die Anforderungen zur Prüfung der Erstattungsfähigkeit digitaler Pflegeanwendungen in der Sozialen Pflegeversicherung (VDiPA) - Bundesgesundheitsministerium." Accessed November 17, 2022.

COUNTRY PROFILE (REGION OPTIONAL)	**GERMANY**
INVOLVED AUTHORITIES	**Bfarm – Federal Institute for Drugs and Medical Devices** DiGA: The National Association of Statutory Health Insurance Funds (**GKV**) DiPA: Social Long-Term Care Insurance (**SPV**)
ASSESSMENT DOMAINS	**DiGA** • Proof of positive care effect • Robustness • Consumer protection • Ease of use • Support for healthcare providers • Medical content quality and patient safety • Privacy and security • Data security requirements • Interoperability **DiPA** • Proof of positive nursing effect • Robustness • Consumer protection • Ease of use • Support for healthcare providers • Medical content quality and patient safety • Privacy and security • Data security requirements • Interoperability
PROCESS	**DiGA** • Manufacturer's application to Bfarm • Evaluation by Bfarm • Result of evaluation: > Refused > Provisional listing for 12 months to gather additional evidence > Listing, including negotiation with national health insurance schemes (GKV) • For products with provisional listing, a review of the evidence will be carried out prior to final listing. **DiPA** • Manufacturer's application to Bfarm • Evaluation by Bfarm • Result of evaluation: > Refused > Listing after negotiation with the Social Long-Term Care Insurance (SPV)

COUNTRY PROFILE (REGION OPTIONAL)	GERMANY	
CRITERIA ON VALUE BASED CARE	**DiGA** *(8)* > Evidence of a positive impact of care, patient-relevant structural and service improvements (new outcomes) It applies to the detection, monitoring, treatment or alleviation of disease. It also applies to the detection, treatment, alleviation or compensation of injury or disability. It aims to support patients' health care activities or to integrate the processes between patients and health care providers, in particular in the areas of: • Coordination of treatment processes, • Alignment of treatment with guidelines and accepted standards, • Adherence, • Facilitating access to care, • Patient safety, • Health literacy, • Patient empowerment, • Coping with the difficulties of everyday life due to illness • Reducing the cost of care and the burden on patients and their families. > Medical benefits (traditional outcomes): • Improvement in health, • Reduced duration of illness, • Improved survival • Improved quality of life **DiPA** *(30)* A nursing benefit reduces impairments to the independence or abilities of the person in need of care or counteracts an increase in the need for care. The nursing benefit provided to the person in need of care must be in at least one of the following areas: • Mobility • Cognitive and communication abilities • Behavioural and mental health problems • Self-sufficiency • Managing and coping independently with the demands and stresses of illness or treatment • Organising daily life and social contacts The nursing benefit can also be paid for household tasks. The nursing benefit can also be used to support family members or other voluntary carers in a way that helps to stabilise the care situation at home.	
ACCEPTANCE OF CLINICAL DATA	☑ Data from populations outside the local market	☐ Data from a similar device
RELEVANT COCIR NTA	ZVEI	www.zvei.org/en
REFERENCES	Provided in the “Legal Framework”- segment of this Country Fiche.	

3.4. SPAIN

The Spanish healthcare system is highly decentralised, with each of the 17 Autonomous Communities (Comunidades Autónomas) overseeing its own healthcare provision. Currently, there is no path to reimbursement for Digital Health Solutions.

However, this does not preclude potential coverage of Digital Health Solutions at the regional level, as the Communities are responsible for allocating public health funds.

In 2022, the Spanish Ministry of Health published a Digital Health Strategy *(31)* to [i] improve patient empowerment, [ii] maximise process value and [iii] innovate in data management so that the national healthcare system can meet sensitive societal demands. However, the Strategy does not address the reimbursement of Digital Health Solutions.

COUNTRY PROFILE (REGION optional)	**SPAIN**	
SCOPE	☑ Medical devices (CE Mark)	☐ Other
REIMBURSEMENT	☑ Statutory Health Insurance	☐ Private insurance
REIMBURSEMENT (additional)		
DHS - TYPE	Any type of DHS that the local health unit decides to purchase. There is no regional or national process.	
DHS - DEFINITION / DESCRIPTION	No definition related to digital health solutions or coverage criteria.	
LEGAL FRAMEWORK	None related to reimbursement or funding of digital health.	
INVOLVED AUTHORITIES	Any healthcare organisation that decides to purchase a digital health solution.	
ASSESSMENT DOMAINS	Not defined.	
PROCESS	Not defined.	
Criteria on Value Based Care	Not defined.	
ACCEPTANCE OF CLINICAL DATA	☐ Data from populations outside the local market	☐ Data from a similar device
RELEVANT COCIR NTA	Fenin	www.fenin.es
REFERENCES	In the absence of relevant framework, no references.	

3.5. SWEDEN

Sweden has a highly regionalised health care system, with 21 regions providing health care and 290 municipalities providing care for the elderly and disabled *(32)*. Interestingly, the national authorities do not have enforcement powers over the regions and municipalities, unless the Swedish Parliament decides otherwise on a case-by-case basis.
Overall, there is currently no national pathway for reimbursement of Digital Health Solutions. However, regional collaboration has contributed to a significant uptake of virtual visits to primary care physicians and disease-specific virtual services. For example, a specific DHS in Sweden generated €14 million in revenue in 2021 by connecting patients with joint and back pain to a physiotherapy service.

In short, there is currently no official pathway of reimbursing Digital Health Solutions in Sweden. However, given that digital health services are booming in the country, it is easy to conclude that it is possible to develop a market for Digital Health Solutions outside of any formal pathway in the country.

COUNTRY PROFILE (REGION optional)	**SWEDEN**	
SCOPE	☑ Medical devices (CE Mark)	☐ Other
REIMBURSEMENT	☑ Statutory Health Insurance	☐ Private insurance
REIMBURSEMENT (additional)		
DHS - TYPE	Any type of DHS that the local health unit decides to purchase. There is no regional or national process.	
DHS - DEFINITION / DESCRIPTION	No definition related to digital health solutions or coverage criteria.	
LEGAL FRAMEWORK	None related to reimbursement or funding of digital health.	
INVOLVED AUTHORITIES	Any healthcare organisation that decides to purchase a digital health solution.	
ASSESSMENT DOMAINS	Not defined.	
PROCESS	Not defined.	
Criteria on Value Based Care	Not defined.	
ACCEPTANCE OF CLINICAL DATA	☐ Data from populations outside the local market	☐ Data from populations outside the local market
RELEVANT COCIR NTA	Swedish Medtech	www.swedishmedtech.se
REFERENCES	In the absence of relevant framework, no references.	

3.6. THE UK

The UK has pioneered the development of frameworks for the evaluation of Digital Health Solutions based on the methodological guidance 'Evidence standards framework [ESF] for digital health technologies [DHTs]' *(6)* first published in 2019 and revised in 2022 to include requirements for AI. The Evidence Standards Framework proposes a set of evidence standards for a wide range of digital health technologies, which will enable evaluators and health and care decision-makers to identify the DHTs that are most beneficial to users and the health and care system. At the same time, this standardised approach to evaluation could reduce the burden on companies by allowing them to present the same information for different evaluators and commissioning decisions. The UK framework provides a comprehensive methodological approach to evaluating different categories of Digital Health Solutions. More recently, NICE has introduced the Early Value Assessment (EVA) programme, which, although not specific to digital health technologies, will enable more rapid assessment of digital health products (37).

The decision to use Digital Health Solutions in England is made independently either by one of the 42 Integrated Care Boards *(33)* that oversee integrated care systems *(34)* or at the level of individual hospital trusts. The Digital Technology Assessment Criteria (DTAC) *(36)* have been introduced by NHS England to provide assurance on the market entry of Digital Health Products. These criteria are publicly available and aim to ensure that Digital Health Solutions meet essential requirements for clinical safety, privacy, technical security, interoperability, and usability/accessibility. In addition, the DTAC can be applied at a local or national level.

Overall, there is currently no national pathway leading to reimbursement for Digital Health Solutions in the UK. However, there is funding available within integrated care systems to support the implementation of digital technologies. It is important to note that this is one-off funding.

COUNTRY PROFILE (REGION optional)	**ENGLAND**	
SCOPE	☑ Medical devices (CE Mark)	☐ Other
REIMBURSEMENT	☑ Statutory Health Insurance	☐ Private insurance
REIMBURSEMENT (additional)		
DHS - TYPE	Any type of DHS that the local health unit decides to purchase. There is no regional or national process.	
DHS - DEFINITION / DESCRIPTION	No definition related to digital health solutions or coverage criteria.	
LEGAL FRAMEWORK	None related to reimbursement or funding of digital health.	
INVOLVED AUTHORITIES	Any healthcare organisation that decides to purchase a digital health solution.	
ASSESSMENT DOMAINS	Digital Technology Assessment Criteria (DTAC) (36)	
PROCESS	Not defined.	
Criteria on Value Based Care	Not defined.	
ACCEPTANCE OF CLINICAL DATA	☐ Data from populations outside the local market	☐ Data from a similar device
RELEVANT COCIR NTA	ABHI	www.abhi.org.uk
REFERENCES	In the absence of relevant framework, no references.	

4. CONCLUSION

Europe is getting older. Europeans are living longer, having fewer children, and wanting to lead active and healthy lives. To promote social inclusion without compromising people's health, European countries are trying to ensure that people have quick and easy access to quality healthcare outside of hospitals. They are also seeking to deploy innovative healthcare solutions, recognising that the integration of deep tech and AI in the delivery of ambulatory care could go a long way in meeting people's evolving healthcare needs.

Adoption of innovation requires a specific environment to flourish. National healthcare systems and coverage conditions can encourage or discourage it. In particular, national health systems that apply the Bismarck model *(1)* tend to link innovation directly to coverage. This allows countries such as Belgium, France, and Germany to create clear pathways for reimbursement of Digital Health Solutions. This is not the case with the Beveridge model of healthcare *(1)* where countries such as the UK, Spain and Sweden are at best developing guidelines.

Finally, Coverage with Evidence Development seems to be the easiest and fastest way to integrate innovation while ensuring that the country's quality and value criteria are met - i.e. the Digital Health Solution can improve outpatient support, as in Germany, or optimise the care pathway, as in Belgium.

Clearly, the French, German and Belgian pathways are only the first positive steps towards the ultimate goal of timely and accurate uptake of healthcare innovation in Europe for the benefit of society as a whole. Other countries, such as Denmark, are determined to also follow their lead *(44)*. We look forward to seeing progress and developments in all European countries.

5. REFERENCES

(1) Kulesher RR, Elizabeth Forrestal E. International models of health systems financing. J Hosp Adm. 2014 May 27;3(4):127. and PNHP [Internet] [cited 2023 Oct 16].
Available from : https://www.pnhp.org/single_payer_resources/health_care_systems_four_basic_models.php

(2) HtaGlossary.net | health technology assessment [Internet]. HtaGlossary.net. [cited 2023 Feb 20].
Available from: http://htaglossary.net/health-technology-assessment

and HTA Regulation [Internet] [citied 2023 Oct 17]
Available from: https://health.ec.europa.eu/health-technology-assessment/regulation-health-technology-assessment_en

(3) COUNCIL DIRECTIVE 93/42/EEC on Medical Devices [Internet]. [cited 2020 Feb 22].
Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31993L0042

(4) REGULATION (EU) 2017/ 745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on Medical Devices [Internet]. 2017 p. 175. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

(5) Integrated care systems explained [Internet]. The King's Fund. 2022 [cited 2023 Feb 20].
Available from: https://www.kingsfund.org.uk/publications/integrated-care-systems-explained

(6) Evidence standards framework for digital health technologies [Internet]. 2022 p. 43.
Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies

(7) Mobile medical applications: filing for reimbursement – RIZIV/INAMI [Internet]. [cited 2023 Oct 30].
Available from: https://www.riziv.fgov.be/nl/professionals/andere-professionals/fabrikant-implant/Paginas/fabrikant-en-verdelers-medische-mobiele-toepassingen-aanmelden.aspx

(8) Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB V [Internet].
Available from: https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/diga_leitfaden.pdf?_blob=publicationFile

(9) MDCG 2019-16 Guidance on Cybersecurity for medical devices [Internet]. 2019.
Available from: https://ec.europa.eu/docsroom/documents/41863

(10) Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med. 2001 Jul;33(5):337–43.

(11) Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care. 1992 Jun;30(6):473–83.

(12) Endpoints used for Relative Effectiveness Assessment: Clinical Endpoints [Internet].
Available from: https://www.eunethta.eu/wp-content/uploads/2018/01/Clinical-endpoints.pdf

(13) Ludewig G, Klose C, Hunze L, Matenaar S. [Digital health applications: statutory introduction of patient-centred digital innovations into healthcare]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2021 Oct;64(10):1198–206.

(14) METHODOLOGICAL GUIDE: Organisational impact map for health technology assessment [Internet]. [cited 2022 Nov 10].
Available from: https://www.has-sante.fr/upload/docs/application/pdf/2021-04/organisational_impact_map_for_health_technology_assessment.pdf

(15) LEVELS OF EVIDENCE Internal validity of randomised controlled trials [Internet].
Available from: https://www.eunethta.eu/internal-validity-of-randomised-controlled-trials

(16) Steckler A, McLeroy KR. The Importance of External Validity. Am J Public Health. 2008 Jan;98(1):9–10.

(17) Stern AD. Advancing digital health applications: priorities for innovation in real-world evidence generation. 2022;4:7.

(18) Medical applications now reimbursed by launching level 3 - mHealthBELGIUM [Internet]. [cited 2022 Nov 9].
Available from: https://mhealthbelgium.be/news/medical-applications-now-reimbursed

(19) First app in level M3 of validation pyramid - mHealthBELGIUM [Internet]. [cited 2022 Nov 9]. Available from: https://mhealthbelgium.be/news/persbericht-duidelijk-financieringskader-nodig-voor-doorbraak-medische-apps-in-belgie-4

(20) Possibility of integrating your applications with the health and reimbursement system - INAMI [Internet]. [cited 2022 Nov 9]. Available from: https://www.inami.fgov.be/fr/professionnels/sante/fournisseurs-implants/Pages/default.aspx

(21) Remboursement de la Télésurveillance [Internet]. G_NIUS. 2022 [cited 2023 Feb 20]. Available from: https://gnius.esante.gouv.fr/fr/financements/fiches-remboursement/remboursement-de-la-telesurveillance

(22) DGOS_Sofiane.M, DGOS_Sofiane.M. Télésurveillance médicale : 2 décrets actent l'intégration de la télésurveillance médicale dans le droit commun [Internet]. Ministère de la Santé et de la Prévention. 2023 [cited 2023 Jan 16]. Available from: https://www.has-sante.fr/jcms/p_3405664/fr/telesurveillance-medicale-2-decrets-actent-l-integration-de-la-telesurveillance-medi- cale-dans-le-droit-commun

(23) Section 1: General provisions relating to supplies and devices covered under medical services (Articles L165-1 to L165-13) - Légifrance [Internet]. [cited 2023 Feb 20]. Available from: https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006073189/LEGISCTA000006172525/#LEGISCTA000006172525

(24) Prise en charge anticipée (PECAN) [Internet]. G_NIUS. 2022 [cited 2023 Feb 20]. Available from: http://gnius.esante.gouv.fr/fr/financements/fiches-remboursement/prise-en-charge-anticipee-pecan. https://has-sante.fr/upload/docs/application/pdf/2023-03/pecan_guide_de_depot_de_dossier.pdf

(25) Assessment principles established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to determine the reimbursement eligibility of medical devices for individual use [Internet]. [cited 2022 Oct 26]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2019-11/assessment_principles_established_by_cnedimts.pdf

(26) Bericht des GKV-Spitzenverbandes über die Inanspruchnahme und Entwicklung der Versorgung mit digitalen Gesundheitsan- wendungen (DiGA-Bericht) [Internet]. [cited 2023 Jan 10]. Available from: https://www.gkv-spitzenverband.de/media/dokumente/krankenversicherung_1/telematik/digitales/2022_DiGA_Bericht_BMG.pdf

(27) BfArM - Digital nursing applications (DiPA) [Internet]. [cited 2022 Nov 17]. Available from: https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Nursing-Applications/_node.html

(28) DiPA - the new digital application in nursing care in Germany [Internet]. IGES Digital. [cited 2022 Oct 12]. Available from: https://digital.iges.com/diga_amp_dipa/dipa_-_digital_application_in_nursing_care

(29) Das Verfahren für digitale Pflegeanwendungen (DiPA) nach § 78a SGB XI Ein Leitfaden für Hersteller und Nutzende [Internet]. [cited 2022 Dec 14]. Available from: https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/DiPA_Leitfaden.pdf;jsessionid=395665A- C466A966CD9B849F35D5200C7.intranet671?_blob=publicationFile

(30) Referentenentwurf des Bundesministeriums für Gesundheit - Verordnung über das Verfahren und die Anforderungen zur Prüfung der Erstattungsfähigkeit digitaler Pflegeanwendungen in der Sozialen Pflegeversicherung (Verordnung zur Erstattungsfähigkeit digitaler Pflegeanwendungen – VDiPA). :72.

(31) DIGITAL HEALTH STRATEGY NATIONAL HEALTH SYSTEM [Internet]. [cited 2022 Nov 3]. Available from: https://www.sanidad.gob.es/ciudadanos/pdf/Digital_Health_Strategy.pdf

(32) Kavaliunas A, Ocaya P, Mumper J, Lindfeldt I, Kyhlstedt M. Swedish policy analysis for Covid-19. Health Policy Technol [Internet]. 2020 Aug 29 [cited 2020 Sep 17]; Available from: http://www.sciencedirect.com/science/article/pii/S2211883720300812

(33) NHS England: Integrated care in your area [Internet]. [cited 2022 Nov 7]. Available from: https://www.england.nhs.uk/integratedcare/integrated-care-in-your-area/

(34) NHS commissioning » Integrated care systems (ICSs) [Internet]. [cited 2022 Nov 7]. Available from: https://www.england.nhs.uk/commissioning/who-commissions-nhs-services/ccg-ics/

(35) NHS Apps Library [Internet]. NHS Digital. [cited 2022 Nov 7].
Available from: https://digital.nhs.uk/services/nhs-apps-library

(36) Digital Technology Assessment Criteria (DTAC) [Internet]. NHS Transformation Directorate. [cited 2022 Oct 12].
Available from: https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

(37) NICE England: Early Value Assessment (EVA) for medtech [Internet]. [cited 2023 Oct 16]
Available from: https://www.nice.org.uk/about/what-we-do/eva-for-medtech

(38) van Kessel A, Mossialos E et al. Digital Health Reimbursement Strategies of 8 European Countries and Israel: Scoping Review and Policy Mapping. JMIR Publications. Published on 29.9.2023 in Vol 11 (2023).
Available from: https://mhealth.jmir.org/2023/1/e49003

(39) MDCG 2023-4 Medical Device Software (MDSW) - Hardware combinations; Guidance on MDSW intended to work in combination with hardware or hardware components (October 2023). [cited 2023 Nov 13]
Available from: https://health.ec.europa.eu/system/files/2023-10/md_mdcg_2023-4_software_en.pdf

(40) German Ministry of Health: Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG) (30 August 2023). [cited 2023 Nov 13].
Available from: https://www.bundesgesundheitsministerium.de/ministerium/gesetze-und-verordnungen/guv-20-lp/digig

(41) French Health Authority (HAS) Positive Evaluation : AVIS RELATIF À UNE ACTIVITÉ DE TÉLÉSURVEILLANCE MÉDICALE – Mis en ligne le 25 oct. 2023 (cited 2023 Nov 28)
Available from: https://www.has-sante.fr/jcms/p_3470263/fr/resilience-pro

Press release of 07th November 2023 by RESILIENCE.care,
Available from: https://telesurveillance.resilience.care/hubfs/CP-Resilience-07112023.pdf?trk=public_post_comment-text

(42) Bfarm – Bundesinstitut for Arzneimittel und Medizinprodukte: The Full DiGA list (cited 2023 Nov 28)
Available from: https://diga.bfarm.de/de/verzeichnis

(43) SVDGV -Spietzenverband Digitale Gesundheitsversorgung: Marktentwicklung digitaler Gesundheitsanwendungen (DiGA-Report) Available from: https://digitalversorgt.de/wp-content/uploads/2024/01/DiGA-Report-2023.pdf

(44) Ministry for the Interior and Health of Denmark: En halv milliard kroner til hjemmebehandling med digitale løsninger (New agreement: Half a billion kroner for home treatment with digital solutions) (cited 2023 Dec 19)
Available from: https://mtrconsult.com/news/funding-500-million-dkk-home-treatment-digital-solutions-denmark#:~:text=Funding%20of%20500%20million%20DKK%20for%20home%20treatment%20with%20digital%20solutions%20in%20Denmark,-27%20Dec%202023&text=In%20December%202024%2C%20the%20Government,treatment%20in%20the%20healthcare%20system
and: https://www.regioner.dk/services/nyheder/2023/december/ny-aftale-en-halv-milliard-kroner-til-hjemmebehandling-med-digitale-loesninger/

GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

COCIR COMPANY MEMBERS:

ACCURAY · AGFA HealthCare · AGFA · aidence (human sense in artificial intelligence) · Alcon · Apple · BARCO · BAYER · Canon Medical · Carestream · CMR Surgical · Dedalus HealthCare Systems Group · Elekta · EOS imaging · Epic · esaote · FUJIFILM · GE HealthCare · HOLOGIC · HUAWEI · iba · IBM · Konica Minolta · LUXIUM Solutions · PHILIPS · SAMSUNG · SERVIER · SIEMENS Healthineers

NATIONAL TRADE ASSOCIATIONS MEMBERS:

AGORIA	Healthtech Finland	SNITEM	bvitg	zvei
BELGIUM	FINLAND	FRANCE	GERMANY	GERMANY
ETOSZ	CONFINDUSTRIA	apormed	FMed	
HUNGARY	ITALY	PORTUGAL	THE NETHERLANDS	
FME	Fenin	Swedish Medtech	TIP GÖR DER	ABHI
THE NETHERLANDS	SPAIN	SWEDEN	TURKEY	UNITED KINGDOM

COCIR Advancing Healthcare

COCIR *How to join us*

COCIR aisbl | Bluepoint Building | Boulevard A. Reyerslaan 80 | 1030 Brussels | Belgium

Tel +32 (0)2 706 89 60 | Email info@cocir.org | www.cocir.org | @COCIR