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

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

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1. INTRODUCTION

Digital Health Solutions (Digital Health Solutions) have inspired numerous initiatives both in the EU Member States and beyond. Some of them are linked to market access uptake and utilization, while others to reimbursement. With regard to Digital Health Solutions reimbursement in particular, different national strategies see different levels of success.

This report is called Market Access Pathways for Digital Health Solutions. It is actually a compendium of Country Profiles. This compendium aims to capture the current reality of national pathways on Digital Health Solutions, with a special focus on those pathways that may lead to reimbursement.
Based on the coordination and know-how of Synergus RWE, the Living Repository was developed with the collaboration of the COCIR's National Trade Associations (NTA) and the COCIR Office.
Finally, the current edition of the 'Living Repository' focuses on the same set of countries addressed by the relevant COCIR publication in late 2020[1], namely:

- Belgium
- France
- Germany
- Spain
- Sweden
- England

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

#MA4DHSs	Market Access for Digital Health Solutions
Beveridge healthcare system	National Health System based on universal health for all citizens financed through taxation *(1)*.
Bismarck healthcare system	Social insurance model based on compulsory coverage financed through employer or individual *(1)*.
CED	Coverage with Evidence Development. A process where reimbursement is provided while additional evidence is being generated. Typically, a program of this kind has a limited period of applicability.
COCIR MA FG	COCIR Market Access Focus Group
DHS	Digital Health Solutions
EC	European Commission
EU	European Union
EU MSs	EU Member States
EUnetHTA	European Network for Health Technology Assessment organisation
HCSs	healthcare systems
HTA	Health Technology Assessment '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)*.
MDD	Medical Device Directive *(3)*
MDR	Medical Device Regulation *(4)*
NICE	National Institute for Health and Care Excellence British organisation providing 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; however, in practice, this is not linked to any evaluation program.
NTAs	National Trade Associations
Pathway	In the scope of this report, pathway is defined as a structured process that leads to a decision regarding recommendation, policy and/or coverage.
QALY	Quality Adjusted Life Year
RCT	Randomized Clinical Trial
RWE	Real World Evidence

2. DIGITAL HEALTH SOLUTIONS: FRAMEWORK

2.1. PATHWAYS AND HEALTHCARE MODELS

In Europe, national healthcare systems are neither organized nor financed in the same way. This diversification has a direct impact on the pathways. For instance, in the Beveridge countries [2] the impact of pathways is rather diffuse, as the decision-making bodies are the budget holders. An illustrative example is the UK, where the National Institute for Health and Care Excellence (NICE) is entrusted with issuing recommendations, but not decisions on the payment or reimbursement of a medical technology and device. This power lies with the Integrated Care Boards[3], which are responsible for budget and commissioning.
Importantly, while the absence of a recommendation could discourage any business in the Beveridge system countries, a positive recommendation cannot be interpreted as a 'funding decision' – which usually requires an additional effort at local level. Overall, in the Beveridge type countries (Table 1), pathways are not clearly linked to reimbursement.

Conversely, in the Bismarck[4] countries, which apply Social Security health models, Digital Health Solutions pathways tend to result in 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.*

Additionally, Table 2, here below, illustrates how different national healthcare systems lead to different outcomes in terms of pathways employed.

PATHWAY (COUNTRY)	**OUTCOME**	**IMPACT ON UPTAKE / REIMBURSEMENT**
Evidence standards framework for digital health solutions (UK) *(6)*	Guidance to DHS developers regarding methodological considerations.	No direct link to uptake or reimbursement.
Mhealth – Level 1 (BE) *(7)*	Apps are registered on a list with products fulfilling CE-mark and GDPR requirements.	No direct link to uptake or reimbursement.
Digital Health Application Regulation (DiGA) (DE) *(8)*	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. SCOPE OF DIGITAL HEALTH SOLUTIONS (DHS)

Digital Health Solutions include a broad range of applications, both stand-alone and integrated to medical devices and diagnostics. Each pathway linked to reimbursement includes a specific description of the type of Digital Health Solutions, applicable to it. For instance, it could determine how the solution should be utilized – as is the case with the German DiGA process, where the Digital Health Solutions should be patient-centric, and without any primary objective to support physicians.

2 Beveridge healthcare system: National Health System based on universal health for all citizens financed through taxation *(1)*.
3 Integrated care systems (ICBs) have the responsibility of allocating the NHS budget and commissioning the healthcare services within the dedicated Integrated Care System, which is defined to a specific region.(5)
4 Bismarck healthcare system: Social insurance model based on compulsory coverage financed through employer or individual *(1)*.

The pathways may also include a specification of the regulatory classification to define the scope of Digital Health Solutions. This can refer to the Medical Device Regulation *(4)* (MDR) or other classification of products.
Table 3 compares the scope of Digital Health Solutions pathways in 3 EU Member States

DHS FUNCTIONAL SCOPE	REIMBURSEMENT PATHWAY FOR DIGITAL HEALTH (Bismarck)		
	BELGIUM	GERMANY	FRANCE
This comparison aims to broadly capture the functional scope of the different pathways that exist. Combining the functional scope with the limitations based on the regulatory classification may lead to a rather narrative definition, whereas there is also the example of Digital Health Solutions with a therapeutic benefit and no limitation in the regulatory classification and thus providing a broad potential scope.			
REMOTE MONITORING	X		X
DHS WITH THERAPEUTIC BENEFIT			X
PATIENT DHS LINKED TO ACTION BY HEALTHCARE PROFESSIONAL			
DHS CENTRED AROUND PATIENT		X	
DIGITAL ASSITANTS 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 PLACEMENT REQUIREMENTS

The EU Medical Device Regulation (MDR) *(4)* provides a clear improvement on Digital Health Solutions general safety, performance, and clinical evaluation process.
However, as products approved under MDD are still allowed to be on the market, this means that not all Digital Health Solutions have undergone the same evaluation procedure. Their differences are reflected in the different market access pathways applied at national level (see Table 4 for additional information).

DHS REGULATORY CLASSIFICATION	REIMBURSEMENT PATHWAY FOR DIGITAL HEALTH (Bismarck)		
	BELGIUM	GERMANY	FRANCE
With the revised Medical Device Regulation, there was a significant change in the classification of software based medical devices, leading to alignment with traditional medical devices. **MDCG 2019-11** Guidance on Qualification and Classification of Software in Regulation **(EU) 2017/745 - MDR** and Regulation **(EU) 2017/746 - IVDR**			
I	X	X	X
IIa	X	X	X
IIb	X		X
III	X		X

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

2.4. DIGITAL HEALTH SOLUTIONS AND SECURITY

Digital Health Solutions (DHS) aim to inform patients of their physical condition while dispatching this information to specific health-care professionals and settings.
The EU Medical Devices Regulation (MDR), with its Implementing Acts and Guidance *(9)* mitigates potential risks related to Digital Health Solutions cybersecurity, data-protection, and interoperability.
Products currently on the market have been approved in accordance with criteria established by the EU Medical Devices Directive (EU MDD). Nevertheless, in addition to the EU MDD criteria, many countries apply further requirements on the safe use of Digital Health Solutions, while others require independent testing in their own countries.

2.5. DIGITAL HEALTH SOLUTIONS AND HEALTH TECHNOLOGY ASSESSMENT

New Digital Health Solutions (DHS) emerge every day promoting their capacity to optimise healthcare delivery. This new reality has created the need for countries to develop adequate processes to correctly assess the benefit, efficiency, and value of Digital Health Solutions.

In this context, national Health Technology Assessment (HTA) *(2)* bodies are commissioned to scrutinise the benefit and value of Digital Health Solutions, thereby contributing to informed policy decision-making, also on coverage and reimbursement. On a broader scale, the European Regulation on Heath Technology Assessment aims at providing a common HTA framework to streamline methodologies and criteria while avoiding duplication of efforts.

In short, by comparing the performance level of a new Digital Health Solutions with the current standard of care and by determining its cost-effectiveness, the HTA examines the overall value of the new Digital Health Solutions, on the basis of which a positive decision on reimbursement could be issued. (see Figure 1).

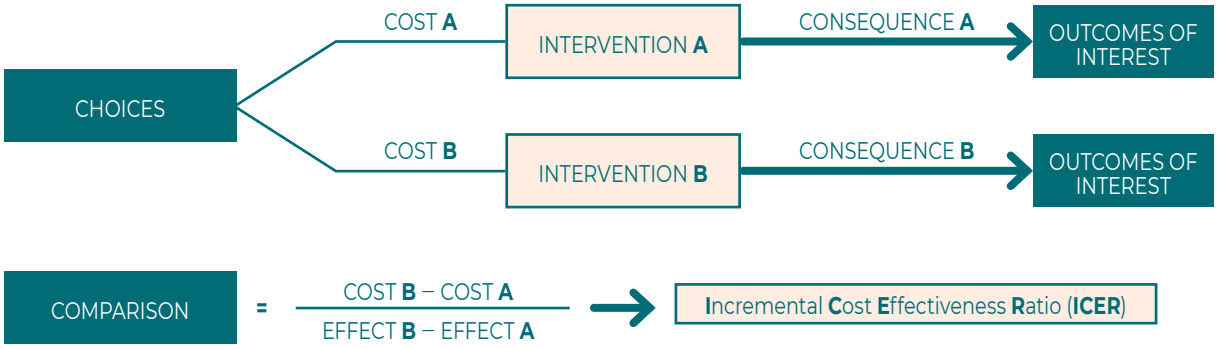

Figure 1 *Cost effectiveness methodology.*

In principle, the HTA for Digital Health Solutions can rely on the improved outcome of interest, the economic consequences, or the combined measure of cost-effectiveness.

To standardize the comparison between different therapeutic areas, the preferred outcome of interest is Quality-Adjusted Life Year (QALY) measured with standardized instruments, such as Euroqol EQ-5D *(10)* or SF-36 *(11)*. The methodological frameworks for evaluation generally include three categories of clinical endpoints: Mortality, Morbidity and Health Related Quality of Life *(12)*.

At national level, recognising the limitation of these traditional categories, the German DiGA process introduced new outcomes relating to improved healthcare delivery, such as adherence, improved adherence to guidelines, and expectation of medical benefits *(13)*.

In the same vein, countries recognise the potential of Digital Health Solutions to enhance healthcare delivery, through improved efficiency. To duly assess the organizational benefits (value) of such Digital Health Solutions, national pathways tend to compare the required resources before and after the Digital Health Solutions implementation. An illustrative example is France and its targeted guidance on how to capture this type of organizational benefit *(14)*.

Table 5 -here below- provides a comparison of the different categories of value and benefit that are considered in different countries.

The clinical trials methodology is a critical part of the evaluations, and must ensure that clinical trials do provide a true result of efficacy *(15)* – usually through well designed Randomized Clinical Trials (RCT).

While the Health Technology Assessment of medicinal products can safely focus on Randomised Clinical Trials, this is not the case for Digital Health Solutions. For medicines, HTA can implement efficacy trials with high internal validity *(16)* – since their mode of action is based on a biological effect, with limited consideration of the specific context in which the trial has taken place.

However, for most Digital Health Solutions, the desired outcomes targets a behavioural change in the patient or a change in healthcare delivery, thus requiring a different mode of action. Such acknowledgement promotes the use of Real-World-Evidence (RWE) *(17)*, which could provide high external validity *(16)* results. Still, numerous methodological considerations need to be taken into account to ensure that such RWE studies can provide a true signal of efficacy.

VALUE / BENEFIT
Traditionally HTA evaluations would focus on reduction of mortality / morbidity and improved quality of life and health economic impact. These outcomes are still essential to assess value. New ways of assessing the value are being developed but there is limited experience in how these translate to the valuation in the reimbursement decision (The comparison and categorization are simplified and do not cover all aspects.)

VALUE / BENEFIT CATEGORIES			
	BELGIUM	GERMANY	FRANCE
Mortality, Morbidity, Quality of Life	X	X	X
Organisational improvements	(X)	(X)	X
Health Economic	X		
Novel patient centric outcomes		X	

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

2.6. EVALUATION OF EVIDENCE

Not all methodological frameworks require the same rigidity in supporting data/evidence to inform evaluation. While some accept only Randomised Clinical Trials (RCT), others prefer comparative data, or Real-World Evidence (RWE)-studies.
When it comes to Digital Health Solutions, pathways may recognise the need to support innovation and apply the approach of Coverage with Evidence Development (CED), based on which only an initial level of evidence is requested for a Digital Health Solutions to enter the market. This initial requirement is followed by an additional one regarding the provision of more conclusive evidence after a defined period.
Table 6 provides an overview of the formal requirements for the different pathways. If a pathway includes more than one reimbursement and coverage decisions, as is the case with Coverage with Evidence Development, these are treated as separate pathways to demonstrate the difference between the stages.

EVIDENCE REQUIREMENTS
For HTA evaluations, Randomized Clinical Trials (RCT) are considered the gold standard. While all countries recognise that different study designs could be used, the question still remains. What approach is methodologically justifiable to inform the decision about viable efficacy? This will in many insistances result in the need for RCT's or very 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

Economic evaluation is a tool to identify, measure, value, and compare the costs and consequences (see Figure 1) of different Digital Health Solutions – in the sense of public health interventions, be it policies or programmes. It can consider both resources used, and health outcomes achieved simultaneously – which is useful in supporting decision-making when resources are limited.
There are four types of economic evaluation: economic impact analysis, programmatic cost analysis, benefit-cost analysis, and cost-effectiveness analysis. All these different methods can be used to evaluate the economic consequences of introducing a new Digital Health Solutions.
Belgium is currently the only country that implements both economic impact and cost-effectiveness analysis for the evaluation of Digital Health Solutions.

3. COUNTRY-REPORTS

3.1. BELGIUM

The mHealth validation pyramid, see Figure 2, was first introduced in 2018. At that time the first two levels of assessment ensured that the software/mobile application is CE-marked as a medical device (level 1) and that is interoperable and safely connected (level 2) *(7)*.

These first two levels of assessment are not linked to reimbursement.

Applications that have completed levels 1 and 2 of the pyramid (see below), and meet the criteria for mobile medical applications within a specific care process, can be potentially reimbursed, either temporarily or permanently.
It should be noted that the intention is not to reimburse applications per se, but rather their use within the context of a specific care process and thereby support the adoption of the digital health technology.
The criteria for the third level, which requires the demonstration of the socio-economic value, were released early 2021 *(18)* and led to the conditional reimbursement of the first Digital Health Solutions in April 2022 *(19)*.

Figure 2 *mHealth pyramid.*

COUNTRY PROFILE (REGION optional)	**BELGIUM**	
SCOPE	☐ Medical devices (CE Mark)	☐ Other
REIMBURSEMENT	☑ Statutory Health Insurance	☑ Private insurance
REIMBURSEMENT (additional)	Reimbursement for Level 3 apps	Reimbursement for Level 1 / 2 / 3 apps by specific insurers
DHS - TYPE	mHealth applications	
DHS - DEFINITION / DESCRIPTION	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. In addition, for products that apply for reimbursement: • allows a healthcare professional to diagnose, to apply a therapy or to monitor a patient, all from a distance via a medical device made for use by the patient in their own environment	
LEGAL FRAMEWORK	Not based on specific legislation.	
INVOLVED AUTHORITIES	The eHealth platform RIZIV/INAMI (the National Institute for Health and Disability Insurance - NIHDI)	

ASSESSMENT DOMAINS	Level 1: CE-marking Level 2: Data protection, interoperability Level 3: Comparative effectiveness and budget impact	
PROCESS	Level 1 (M1) determines the basic criteria for an app. Three criteria are applicable: • CE declaration as a medical device is submitted • Voluntary notification of the mobile app to the Federal Agency for Medicines and Health Products (FAMHP), during which the CE marking and the compliance with the rules and regulations for medical devices are confirmed and can be checked • The app and the parent company declare that they comply with the EU General Data Protection Regulation (GDPR) Level 2 (M2) is based on the interoperability and connectivity to the basic services of the eHealth platform. Mobile healthcare apps that are approved as M2: • meet the basic criteria of level 1 • have been submitted to a risk assessment (developed by an independent organisation and included in mHealthBelgium) after which they have proven to meet all imposed criteria regarding authentication, security and the use of local e-health services by means of standardised tests (if applicable) Level 3 (M3) is reserved for apps for which the socio- economic added value has been demonstrated and which are financed, after approval by the NIHDI of their funding request. Level 3 is divided in M3 light (CED) where there is a temporary reimbursement and M3 where there is evidence for a permanent inclusion.	
Criteria on Value Based Care	From INAMI notification form *(20)*: • Relevance of target population • How does the product impact the care pathway? • Comparative effectiveness regarding quality of care or quality of life for the patient. • Budget impact • Cost-effectiveness. (Foreign studies require justification to applicability in 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	mhealthbelgium.be/en	

3.2. FRANCE

France has rolled-out different pilot programmes to evaluate different models for Digital Health Solutions reimbursement. They are currently in the process of moving from the pilot phase to a permanent model for the reimbursement of Digital Health Solutions for remote monitoring.
Though the final regulation for the new process has not been published yet (March 2023), the basic principles are publicly available. With the imminent introduction of the new pathways and withdrawal of the temporary ones, we hereby outline what is currently known about the new pathways.

REMOTE MONITORING (LATM)

Through the ETAPES programme, several pilot projects have been introduced since 2009, with the aim of reimbursing remote monitoring solutions. The scope of these solutions is limited to remote monitoring with no clear therapeutic effect.
The experience from these pilots has resulted in the development of a "liste des activités de télésurveillance médicale" (LATM) *(21)*, a new permanent pathway for remote monitoring solutions. The relevant regulation was released on 30 December 2022 *(22)*.
Initially, the LATM pathway will cover only the five clinical indications previously included in ETAPES:

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

France is currently developing the list of criteria for the evaluation of Digital Health Solutions targeting these five (5) diseases, so that these can be reimbursed in accordance with a unified tariff per category.
New disease areas will be introduced at the request of companies wishing to register a specific product or brand. For the first products in a new category, an individual tariff will be set. When there are sufficient products within a given category, a specification for a generic performance can be established resulting in a unified tariff per category.

THERAPEUTIC DIGITAL HEALTH SOLUTIONS (LPPR)

Digital Health Solutions with intended therapeutic or diagnostic purpose can be registered in the Register of Reimbursable Products and Services[5]– LPPR) *(23)* .
As a reminder, Digital Health Solutions are considered 'medical aids', according to Title 1 of the legislation on LPPR *(23)*, and therefore their evaluation process is the same as for the traditional medical devices – that is via well-designed randomized clinical trials (RCT) demonstrating a meaningful effect regarding reduced mortality, morbidity, disability or improved quality of life.
Occasionally, France can also accept the use of non-randomized data, and in particular when it is impossible to run an RCT or when a novel therapy can establish a clear signal of the Digital Health Solutions effect.

COVERAGE WITH EVIDENCE DEVELOPMENT

Inspired by the new fast-track reimbursement in Germany (DiGA), France will introduce a new pathway for Coverage with Evidence Development though a programme called *Prise en charge anticipée* (PECAN) *(24)*.
This new pathway could provide conditional reimbursement to Digital Health Solutions for a certain period, during which the technology developer would work on the required evidence.
The timeframe is defined as nine (9) months for products in the LATM listing *(24)* and 6 + 6 months for products in the LPPR one. *(24)*
The final regulation is not yet published, but is expected to be implemented in 2023 based on information from SNITEM[6], the French National Trade Association representing the Medical Devices Industry and COCIR member.

COUNTRY PROFILE (REGION optional)	**FRANCE**	
SCOPE	☑ Medical devices (CE Mark)	☐ Other
REIMBURSEMENT	☑ Statutory Health Insurance	☑ Private insurance
REIMBURSEMENT (additional)		

5 Liste des Produits et Prestations Remboursables , revue à l'article L. 165-1 du Code de la sécurité sociale
6 SNITEM: https://www.snitem.fr/

DHS – TYPE	**PECAN** (Prise en charge anticipée): Products that will be reimbursed through LATM (without existing specification) or LPPR **LATM** (liste des activités de télésurveillance médicale): Remote monitoring **LPPR** (Liste des Produits et Prestations Remboursables 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 there is no evidence to date to qualify for a 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/LEGIARTI000044565986/2022-09-01 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 requirement list is under development for defined categories of products. **LPPR** *(25)*: • Product benefit • Public health benefit	
PROCESS	**All pathways** require that the product undergoes a separate cybersecurity evaluation. **PECAN:** • Submission of a simplified dossier to request compensation (a lower payment than what is expected when reimbursed) during a time period of 6-12 months while the missing evidence is generated. • At the end of the period a full dossier is submitted for the respective LATM / LPPR process. **LATM:** • For products where there is an existing specification, a simplified registration is required to demonstrate that the product meets the requirements. • For products without a specification, a more extensive evaluation will be carried out. **LPPR:** • Submission of dossier to HAS resulting in an assessment of the added clinical value. • Based on this there will be a negotiation with CEPS about the reimbursement tariff for the product.	
CRITERIA ON VALUE BASED CARE	**LATM**: • No relevant criteria for 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 is a frontrunner in the establishment of a pathway for Digital Health Solutions reimbursement. This pathway, called DiGA, was launched in September 2021 and raised high interest from Digital Health Solutions developers – with 160 applications in total. A summary of the current status is provided below (January 2023):

- 37 individual DHS products by different companies are included in the DiGA list, either temporary or permanently.
- 15 applications have resulted in a negative conclusion of the evaluation.
- 5 applications have been temporarily included, but later excluded due to lack of evidence.
- 87 applications have been withdrawn by the developer.
- 16 applications are currently in the process of being evaluated by the relevant national authority, Bfarm[7], for potential inclusion in DiGA.

In its latest review of the DiGA pathway the National Association of Statutory Health Insurance Funds (GKV) recognized the potential of Digital Health Solutions, while highlighting the limitations in the Digital Health Solutions evaluation and reimbursement. *(26)*.

In the same report, GKV *(26)* provided useful information on DiGAs. More specifically, in 2022 the total revenue from the use of DiGAs amounted to €55 million. DiGAs targeted different sizes of patient groups – from 10 to 12,000 patients. During the phase of temporary reimbursement, the tariffs for the DiGAs reimbursement varied between €119 and €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 the DiGA one, with the exception that DiPA does not provide for 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 centred on patients, possibly including treating doctors 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 caregivers or outpatient nursing care facilities *(28)*.	

7 BfArM https://www.bfarm.de/DE/Home/_node.html

DHS - DEFINITION / DESCRIPTION	**DiGA** *(8)* • Medical device of risk class I or IIa [according to Medical Device Regulation (MDR) or, within the scope of the transitional provisions of the MDR, according to Medical Device Directive (MDD)]. • The main function of DiGA is based on digital technologies. • The DiGA is not a digital application that merely serves to read or control 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 on prevention). • The DiGA is shared by the patient or by the healthcare provider and the patient, i.e. applications that are only used by the physician to treat patients ("practice equipment") are not DiGA. • The DiGA does not contain any benefits that are excluded under the Third Chapter of the German Social Code, Book V or on which the Federal Joint Committee has already issued a negative decision under § 92, 135 or 137c. **DiPA** *(29)* • For products where the functionality substitutes a medical device per the definition in MDR; they should be CE-marked. • Additional products that are outside the scope of a medical device may also be included. • DiPA is essentially based on digital technologies (software). • A DiPA 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 supplementary support services required for the DiPA. The DiPA is not a digital application that merely serves to read or control a device. • The DiPA serves the purpose of reducing the impairments of independence or the abilities of the person in need of care or counteracting an aggravation of the need for care and thus revealing its nursing benefit. • DiPA can be used by care recipients alone or by care recipients interacting with family members, other volunteer caregivers, and licensed care or support services. • The DiPA can also support family caregivers or other volunteer caregivers in caring for the person in need of care or in managing the household. However, the prerequisite is that the DiPA serves to stabilize the home care situation of the person in need of care. • DiPA is designed to support those in need of care exclusively in a home context.
LEGAL FRAMEWORK	**DiGA** • 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.
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**: • Evidence of positive care effect • Robustness • Consumer protection • User-friendliness • Support for healthcare providers • Quality of medical content and patient safety • Data protection • Data security requirements • Interoperability **DiPA**: • Evidence of positive nursing effect • Robustness • Consumer protection • User-friendliness • Support for healthcare providers • Quality of medical content and patient safety • Data protection • Data security requirements • Interoperability

PROCESS	**DiGA**
	• Application by manufacturer to Bfarm
	• Evaluation by Bfarm
	• Result from evaluation:
	  • Denied
	  • Preliminary listing for 12 months to develop additional evidence
	  • Listing including negotiation with the national statutory health insurance (GKV)
	■ For products with preliminary listing, a review of the evidence will be carried out prior to final listing.
	DiPA
	• Application by manufacturer to Bfarm
	• Evaluation by Bfarm
	• Result from evaluation:
	  • Denied
	  • Listing including negotiation with the Social Long-Term Care Insurance (SPV)

CRITERIA ON VALUE BASED CARE	**DiGA** *(8)* • Evidence of positive care effect, patient relevant structural and healthcare delivery improvements (new outcomes) It applies in the course of detecting, monitoring, treating or mitigating disease or detecting, treating, mitigating or compensating for injury or disability. It is designed to support patients' healthcare activities or to integrate the processes between patients and healthcare providers, including in particular the areas of: • Coordination of treatment procedures, • Alignment of treatment with guidelines and accepted standards, • Adherence, • Facilitating access to care, • Patient safety, • Health literacy, • Patient sovereignty, • Coping with difficulties in everyday life caused by illness • Reduction of the therapy-related cost and burden on patients and their relatives. • Medical benefit (traditional outcomes): • Improvement of the state of health, • Shortening of the duration of illness, • Improved survival • Improvement in the quality of life **DiPA** *(30)* A nursing benefit reduces impairments of the independence or abilities of the person in need of care or counteracts an aggravation of the need for care. The nursing benefit for the person in need of care must be given in at least one of the following areas: • Mobility • Cognitive and communication skills • Behaviours and psychological problems • Self-sufficiency • Coping with and independently dealing with illness or therapy-related requirements and stresses • Shaping everyday life and social contacts In addition, the nursing benefit may also be given in the area of household management. A nursing benefit can also support caring relatives or other voluntary caregivers through the digital application in a way that serves to stabilize the home care situation.	
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 decentralized, and each of the 17 Autonomous Communities (Comunidades Autónomas) oversees its own healthcare provision. There is currently no pathway establishing reimbursement for Digital Health Solutions.

This, however, does not preclude a potential Digital Health Solutions coverage, since the Communities are responsible for the allocation of funds - including for public health.

In 2022, the Spanish Ministry of Health has published a Digital Health Strategy *(31)* incorporating the strategic objectives for [i] empowering and involving patients, [ii] maximising the value of processes, and [iii] adopting data management innovation, in order to adapt the healthcare system to the current societal demands.
Nevertheless, the Strategy does not outline any pathways for Digital Health Solutions reimbursement.

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 healthcare unit determines to buy. No regional or national process exists.	
DHS - DEFINITION / DESCRIPTION	No definition related to digital health solutions and the decision to fund.	
LEGAL FRAMEWORK	None related to reimbursement or funding of digital health.	
INVOLVED AUTHORITIES	Any healthcare organisation choosing 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 highly regionalized healthcare systems, with 21 regions providing healthcare and 290 municipalities providing care for the elderly and disabled *(32)*. Interestingly, the national agencies do not have enforcement capacity on regions and municipalities, unless the Swedish Parliament decides otherwise on a case-by-case basis.
Overall, there is currently no national pathway leading to Digital Health Solutions reimbursement. However, regional collaboration has contributed to a significant uptake of virtual visits to primary care doctors, and disease specific virtual services. As an example, in 2021, a specific Digital Health Solutions in Sweden had a turnover of €14 million by connecting patients that suffered from joint and backpain with a service of physiotherapists.

In conclusion, currently there is no pathway reimbursing Digital Health Solutions in Sweden. However, the possibility of developing a market for Digital Health Solutions outside a formal pathway is real - considering that digital health services are booming 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 healthcare unit determines to buy. No regional or national process exists.	
DHS - DEFINITION / DESCRIPTION	No definition related to digital health solutions and the decision to fund.	
LEGAL FRAMEWORK	None related to reimbursement or funding of digital health.	
INVOLVED AUTHORITIES	Any healthcare organisation choosing 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 to assess Digital Health Solutions based on the methodological guidance "Evidence standards framework [ESF] for digital health technologies [DHTs]" *(6)* published for the first time in 2019, and revised in 2022. The ESF proposes a set of evidence standards for a wide range of DHTs, based on which evaluators and decision makers in the health and care system can identify the DHTs that are most beneficial to users and to the health and care system. In parallel, this standardised approach to evaluations could ease the burden on companies because they could present the same information for different evaluators and commissioning decisions.

Though the UK framework provides a comprehensive methodological approach to the evaluation of the different Digital Health Solutions categories, this has no link to reimbursement decisions.
Overall, there is currently no national pathway that leads to reimbursement of Digital Health Solutions in the UK.
Importantly, the decision to utilize a Digital Health Solutions in England is determined independently by one of the 42 Integrated care boards *(33)* overseeing the Integrated care systems *(34)*.

On another level, the NHS developed an 'app library'. This platform listed those apps proven safe for purchase by the NHS after an initial basic assessment. As of December 2021, this library has been decommissioned *(35)* and replaced by the Digital Technology Assessment Criteria (DTAC) *(36)*. These criteria are publicly available and aim to ensure that Digital Health Solutions respect the basic requirements regarding clinical safety, data protection, technical security, interoperability, and usability/accessibility.
Lastly, the centralized evaluation of NHS apps has been replaced by a de-centralised one, where the individual NHS entities ensure that their acquired Digital Health Solutions fulfil the relevant requirements.

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 healthcare unit determines to buy. No regional or national process exists.	
DHS - DEFINITION / DESCRIPTION	No definition related to digital health solutions and the decision to fund.	
LEGAL FRAMEWORK	None related to reimbursement or funding of digital health.	
INVOLVED AUTHORITIES	Any healthcare organisation choosing 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	ABHI	www.abhi.org.uk
REFERENCES	In the absence of relevant framework, no references.	

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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).

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