A comparison of the reimbursement of digital therapeutics in France, Germany, and the UK

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Objective

Digital therapeutics (DTx) deliver medical interventions directly to patients using evidence-based, clinically evaluated software to treat, manage, or prevent diseases or disorders. DTx represent a novel and rapidly evolving category of health technology. Validated and effective DTx can be an attractive opportunity for public health systems to improve health outcomes across large patient populations at relatively low cost.

The aim of this study was to compare health technology assessment (HTA) and reimbursement of DTx in France, Germany, and the UK.

Methods

DTx are seldom differentiated from other digital health technologies (DHTs) such as telemedicine and connected care[1]. Directory submissions for the National Institute for Health and Care Excellence (NICE), Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDiMTS), and Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) were searched systematically to identify the broader category of DHTs. Interventions were then classified as DTx based on the Digital Therapeutics Alliance definition (**Figure 1**). Individual HTAs of DTx were reviewed for final decisions or recommendations.

Figure 1: Foundational principles of digital therapeutic products, according to the Digital Therapeutics Alliance

- Prevent, manage, or treat a medical disorder or disease
- Produce a medical intervention that is driven by software
- Incorporate design, manufacture, and quality best practices
- Engage end users in product development and usability processes
- Incorporate patient privacy and security protections
- Apply product deployment, management, and maintenance best practices
- Publish trial results inclusive of clinically-meaningful outcomes in peer-reviewed journals
- Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use
- Make claims appropriate to clinical evaluation and regulatory status
- Collect, analyze, and apply real-world evidence and/or product performance data

Note: This figure was re-created from the Digital Therapeutics Alliance[2].

Results

In France, DHTs are assessed by CNEDiMTS using the same process as for all other medical devices. Most DHTs monitored cardiovascular conditions using implantable devices (89%). Of those that met the DTx definition (2%), CNEDiMTS concluded one intervention had insufficient therapeutic value (due to insufficient evidence), one provided moderate added benefit, and one provided minor added benefit (**Table 1**).

In 2020, NICE established a pilot project for assessing DHTs in the UK; medical technology Zio® XT was the first product assessed using this framework. Assessments of two DTx are currently in progress: Sleepio and myCOPD (**Table 1**). A targeted search also identified NICE advice – a form of evidence summary rather than reimbursement assessment – for 14 psychiatry DTx.

Table 1: A summary of interventions assessed by CNEDiMTS and NICE that meet the DTx definition

	Intervention	Description	Therapeutic area	HTA decision
CNEDiMTS	Moovcare® Lung	Remote monitoring software for lung cancer relapses	Oncology	Therapeutic value: Sufficient Added benefit: Moderate (ASA III)
	CORDIVA	Remote monitoring of chronic heart failure patients using a connected device	Cardiovascular	Therapeutic value: Insufficient
	DIABEO®	An application for diabetes patients. Functions include an electronic patient diary, remote monitoring, and capturing data from connected devices	Endocrinology (Diabetes)	Therapeutic value: Sufficient Added benefit: Minor (ASA IV) in Type 1 diabetes only
NICE	Zio® XT	Remote ECG monitoring service used to detect cardiac arrhythmias, composed of a wearable ECG device and a software algorithm for analysis. Results are sent to the patient's clinician	Cardiovascular	Recommended
	myCOPD	Online COPD self-management application, accessible on smart-phones and tablets	Respiratory	Pending
	Sleepio	Designed to help adults with poor sleep using a cognitive behavioral therapy approach	Sleep disorders	Pending

ASA, amélioration du service attendu; CNEDiMTS, Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé; COPD, chronic obstructive pulmonary disease; ECG, electrocardiogram; HTA, health technology assessment; NICE, National Institute for Health and Care Excellence.

In May 2020, Germany introduced a reimbursement process specific to DHTs, via BfArM. Germans covered by statutory health insurance can be prescribed approved digital health applications (digitale Gesundheitsanwendungen; DiGA)[3]. Manufacturers must apply to BfArM to have their technology listed in the DiGA directory in order to have it prescribed and reimbursed[3]. Of the assessments completed, 21% achieved reimbursement, 5% had a negative outcome, and 43% of applications were withdrawn. All reimbursed products met the DTx definition; most were psychiatry interventions (53%). 21% of reimbursed products achieved permanent listing in the DiGA directory and demonstrated an improvement of health status (**Table 2**).

Table 2: A summary of interventions submitted for listing in BfArM's DiGA directory (as of June 2021)

	n	%
Number of applications	81	
Positive decisions	17	21%
Negative decisions	4	5%
Applications withdrawn	35	43%
Assessments in DiGA directory	17	21%
Number of DTx	17	100%
Therapeutic area of DTx in DiGA directory		
Psychiatry	9	52.9%
Oncology	2	11.8%
Neurology	2	11.8%
Cardiovascular	1	5.9%
Audiology	1	5.9%
Endocrinology (obesity)	1	5.9%
Musculoskeletal	1	5.9%

DiGA, digitale Gesundheitsanwendungen; DTx, digital therapeutics.

Discussion & Conclusions

HTA and reimbursement of DTx are at different stages of development across three major European countries – France, Germany, and the UK. Germany has reimbursed the most DTx, reflecting the alignment between the DTx definition and BfArM's assessment criteria for DiGA products. France uses the same pathway for DTx as for all other medical devices (CNEDiMTS assessment) but has assessed very few DTx to date. The assessment of DTx by NICE is less well-defined than in France or Germany, but there is a current initiative to further develop process and methods specific to DTx. The assessment route in France is also expected to evolve and become more distinct as more DTx are introduced.

References

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[3]Bundesinstitut für Arzneimittel und Medizinprodukte. 2020. The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V. A Guide for Manufacturers, Service Providers and Users [online]. Available at: https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.html?nn=708506 [Accessed: 12 October 2021]