Coverage With Evidence Development as a Potential Solution for the Reimbursement of Digital Therapeutics (DTx)? A Systematic Review of Pathways to Inform Reimbursement Decisions in the EU5

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INTRODUCTION

Digital Therapeutics (DTx) are patient-facing, evidence-based therapeutic interventions driven by software to prevent, manage, or treat a medical disorder or disease.

DTx can be utilized as a standalone therapy or in combination with analogue therapy options.

DTx are one promising type of innovation, which could lead to a paradigm shift in the delivery of health services.

METHOD

The primary objective of this research was a comparison of pathways for informed reimbursement decisions of DTx solutions across the five major European healthcare systems (EU5).

Medline, Embase, Scopus and Web of Science were systematically searched.

Conclusion

DTx require new pathways to inform reimbursement decisions.

Due to the disruptive nature of DTx, authorities in Germany, France, the UK and regions of Spain established separate health technology assessment (HTA) pathways. Italy is currently designing a designated HTA pathway for DTx.

The compatibility regarding regulatory and technical requirements across national pathways is high. Guidelines on the transferability of evidence across countries could help to ensure access to DTx across major European countries.

Coverage with evidence development approaches help to foster incentives for investments in these new treatment approaches, guarantee evidence-based coverage decisions and ensure access to these innovative therapies for patients.

Results

35 records published until 15/02/2024 were included in the synthesis.

The table on the right illustrates the transferability of requirements from the German (DiGA) pathway to the French (PECAN) pathway.

These newly designed pathways incorporate coverage with evidence development mechanisms. Manufacturers of DTx already receive reimbursement while they are still collecting data on the long-term efficacy.

The assessment frameworks for national HTA incorporate regulatory, technical and evidence requirements. DTx manufacturers need to comply to these requirements to be eligible for reimbursement within the statutory health insurance systems.

Requirements	Description	Transfer: Germany (DiGA fast-track) to France (PECAN process)
Procedural Requirements	Application documents Main HTA stakeholders	For the national HTA process of DTx, a single central application to BfArM is required in Germany. In France, two separate applications in French must be submitted via the Convergence platform and Evatech.
Product Requirements	Definition of DTx	A patient-centered app for individual use with a medical purpose that meets DiGA requirements will likely also satisfy PECAN requirements for DMD.
Technical Requirements	Data security Data protection Interoperability	Adherence to the latest technical requirements for DiGA, combined with the implementation of user identification and authentication features according to French standards, will likely ensure eligibility for the PECAN process.
Regulatory Requirements	Certification	A valid CE mark under MDD/MDR is a prerequisite for both the DiGA fast-track and PECAN processes.
Evidence Requirements	Medical evidence	An ongoing study is necessary for the PECAN process, with two options available: 1. Use the DiGA study (Risk: Transferability of care context might not be accepted). 2. Conduct a new small-scale study in France. It is recommended to hold an advisory meeting with HAS to discuss whether the ongoing DiGA study or a separate study can be used for the PECAN process. A strategic decision is needed on whether to initiate a new study in France.
	Organization of care	There are differences between the German definition of pSVV and the French definition of organizational benefits for patients. A separate study to demonstrate organizational benefits is necessary if the manufacturer wishes to claim them.
	Economic evidence	Economic evidence is required for the PECAN process, and a French study can also be used to generate this economic evidence.

BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte

CE, Conformité Européene (eng. European Conformity)

CED, Coverage with Evidence Development

DiGA, Digitale Gesundheitsanwendung (eng. Digital Health Application)

DMD, Digital Medical Device

DTx, Digital Therapeutics

HAS, Haute Autorité de Santé

HTA, Health Technology Assessment

MDD, Medical Device Directive

MDR, Medical Device Regulation

PECAN, Prise en charge anticipée numérique

pSVV, Patientenrelevante Struktur- und Verfahrensverbesserung (eng. patient-relevant structural and procedural improvements)

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