Evaluation and reimbursement of digital therapeutics in Germany, France, Belgium and England

PT21

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INTRODUCTION

- Digital Health Therapeutics (DTx) aim to treat, prevent or manage specific conditions through mobile-based software
- Payers are increasingly acknowledging DTx's potential in healthcare delivery, resulting in the development of country-specific reimbursement frameworks
- The objective of this analysis is to compare and contrast the objectives, methodology and eligibility of four established DTx reimbursement frameworks: German DiGA fast track, French PECAN fast track, Belgium mHealth Pyramid, and English Early Value Assessment (EVA)

METHODS

Scientific publications and web pages of DiGA, PECAN, mHealth Pyramid and the EVA were reviewed to extract data on the assessed processes

Figure 1. Methodology used in this research

Data extraction cutoff date: 1st October 2023

RESULTS

Analysis shows that the assessed frameworks differ in objectives, requirements and methodologies.

Figure 2. Comparison of DTx assessment frameworks across Germany, France, Belgium, and the UK

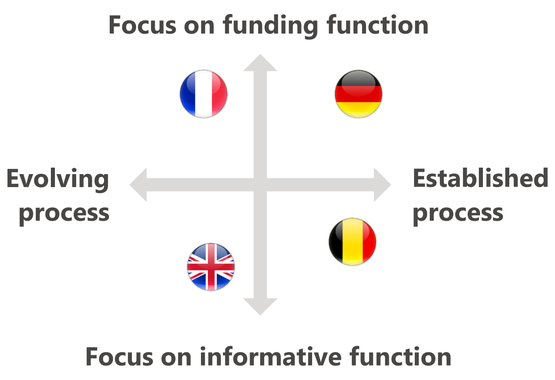
	DiGA	PECAN	mHealth validation pyramid	EVA
Overview	**Aim to accelerate reimbursement for eligible DTx during evidence generation phase**		**Categorizes DTx based on functionality and compliance, offering funding only to those reaching highest criteria level**	**Evaluates selected by NICE medical technologies to provide recommendations for use within NHS while evidence is generated**
	CE mark mandatory, country-specific safety and interoperability criteria must be met			
Eligibility criteria	DTx - MD risk class I and IIa*	• DTx - all MD risk classes; • Telemonitoring solutions	• Basic level: DTx that enables sharing patient information with HCP • Reimbursement level: DTx that enables remote diagnosis, therapy, or monitoring by healthcare providers	Technologies are selected by NICE based on: • Potential for patient and system benefit in an area of national unmet need • Need of further data collection
What is reviewed to inform funding	Medical benefit or patient-relevant improvement of structure and process	Innovative clinical or organizational benefit	Socio-economic value	Benefit to patients, and/or the healthcare system
Required evidence type	Comparative study (may be in planning phase for provision listing)	Clinical trial** ongoing at the time of assessment	Various accepted: RCT, RWE, expert opinions, etc	Evidence in a published format (type undefined)
Evidence generation support	12-month conditional reimbursement supporting completion of study		No support offered	Identifies key gaps in evidence and assists in RWE collection planning
Pricing considerations	• 12-month free pricing • Negotiated price after	• 12-month fixed price** • Negotiated price after	• Price determined as a part of the health care process	• Does not impact price but states whether it is good use of healthcare resources
Evaluations conducted to date	• 40 DTx reimbursed, including: • Mental health – 18 • Musculoskeletal disorders – 5 • Oncology - 4	• Process only introduced in 2023 • 1 DTx reimbursed (oncology)	• 37 DTx in the validation pyramid • 1 DTx temporarily reimbursed (orthopedic rehabilitation)	• 22 DTx evaluated, 13 recommended (Only DTx focused on mental health assessed)
Other assessment Routes	No	Yes (direct LPPR route to national reimbursement)	No	Yes (full NICE MTG on national level, local reimb. assessments)

*Inclusion of IIb class planned; ** Details to be announced

CONCLUSION

- Countries are taking diverse approaches with varying evidence requirements for assessing the value of DTx, in contrast to the unified EU HTA initiative
- This divergence forces companies to invest substantial local resources to facilitate patient access to DTx solutions

Figure 3. Comparison of DTx framework function with the establishment of the process



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All web sources accessed 13th October 2023

Abbreviations: *DTAC: Digital Technology Assessment Criteria; DiGA: Digital Health Applications; EVA: Early Value Assessment; DTx: Digital therapeutic; HCP: Healthcare professional; LPPR: List of products and services; MD: Medical device; MTG: Medical technologies guidance; NICE: The National Institute for Health and Care Excellence*

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