Digital therapeutics in Europe: a structured review of reimbursement and access pathways

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Background and Objective

- Digital therapeutics (DTx) represent novel treatment options that can offer effective patient care and support efficient healthcare delivery – however, reimbursement and uptake remain a key barrier to adoption
- Our aim was to conduct a scoping review of reimbursement and access processes for DTx in major European markets, based on real-world insights and published literature
- We developed a structured framework to support market access planning for DTx based on the identified common challenges associated with these processes

Methods

- Qualitative primary research was conducted with 13 stakeholders based in six countries (Belgium, Italy, Netherlands, Portugal, Spain, UK) operating in roles supporting market access activities for DTx
  - Structured interviews were conducted based on a discussion guide that covered DTx reimbursement and funding pathways, key decision makers and influencers, evidence needs, and DTx landscape
- Additionally, secondary research (a targeted literature search) was carried out to identify publications on DTx policy and reimbursement in Europe

Results

To date, only some countries have national frameworks for DTx assessment and reimbursement*

	National assessment framework	National reimbursement pathway	Available funding mechanisms
Belgium	DTx value evaluation through mHealthBelgium Validation Pyramid[1]	Apps in Level M3 of Validation Pyramid reimbursed by payers	Centralised funding for mHealth apps
France	PECAN frameworks for DTx[2]	5 year national listing	Covered by public health insurance
Germany	DiGA process; standalone DTx evaluated by BfArM[3]	All listed DiGA are reimbursed	GKV-SV centralised funding for DiGA
Italy	X	X	X
Netherlands	X	X	Covered by individual health insurers
Portugal	X	X	Potential for regional reimbursement
Sweden	X	X	Evidence of limited regional reimbursement
Spain	X	X	X
UK	NICE evidence standards framework for digital health technologies[4]	X	Can be funded locally by Integrated Care System

*Table based on Fassbender et al[5] and supplemented by primary research

There is a lack of formal assessment and decision-making processes for DTx at sub-national levels

Participants from all countries highlighted:

- The importance of targeting hospitals/clinics that may make decisions on pilot studies or local funding, focusing on sites with:
  - Specific DTx interest (e.g. specialist centers, prior DTx use)
  - Known clinicians to become ambassadors for the DTx
- Private healthcare as a potential funding route, with advantages over public systems, including autonomy and greater openness to new technologies
- Alternative potential funding routes including pharmacies, employers, patient organizations, and direct to consumer
- Multiple funding routes may need to be targeted for a given DTx

Decision makers and influencers for DTx are similar to those for other healthcare technologies

- Key decision makers and influencers for DTx: HTA bodies, payers, KOLs, budget holders, HCPs, hospital department leads
- However, participants from all countries highlighted a lack of understanding at every level of healthcare systems about the role and nature of digital health, including DTx
- In all countries, participants emphasized the importance of engaging with DTx clinical ambassadors who will increase awareness and advocate for local funding
- Technical leads at local sites may need to be engaged, who will want to know how the DTx fits with IT and patient data infrastructure
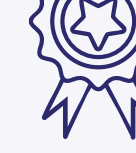
Evidence needs for DTx are aligned with requirements for other healthcare technologies

- Decision making will require evidence of unmet need, clinical trial data, and economic data
- Specific considerations were highlighted for local decision makers:
  - They will typically want to understand DTx value in the context of current pathways of care
  - Business cases that consider HCRU and care efficiency may by particularly impactful

Conclusions

- Despite variation in market access pathways in different countries, common challenges in securing reimbursement and driving uptake of DTx were identified:

  - A lack of understanding of digital health across healthcare systems

  - A lack of established pathways for assessment and reimbursement of DTx

  - The need to consider multiple, fragmented funding routes for DTx products

  - Unique characteristics of DTx products that mean route(s) to market, key stakeholders and strategies may vary considerably product to product

  - Evidence requirements (e.g. need for RCT data) that may be challenging to meet given the nature of development programs for many DTx products

- Taking account of these challenges, we propose a framework that defines a structured approach to planning and strategizing for DTx market access activities in European markets

Navigating complexity: a framework for DTx market access planning

- **Understand reimbursement and funding pathways for DTx**
  What reimbursement and funding route(s) are available for the DTx product?

- **Identify key stakeholders**
  For each funding, who are the relevant stakeholders and what are their priorities?

- **Determine evidence needs**
  What evidence will stakeholders need to understand DTx product value?

- **Communicate product value**
  What messaging will best demonstrate DTx product value to each stakeholder?

- **Support DTx and product landscape**
  What policy and engagement activities could support the DTx landscape?

- **Setting up for success**
  What challenges might be encountered? What can proactively address these?

References: 1. https://mhealthbelgium.be/validation-pyramid; 2. https://gnius.esante.gouv.fr/en/financing/reimbursement-profiles/digital-advance-care-pecan; 3. https://www.bfarm.de/EN/Medical-devices/ Tasks/DiGA-and- DiPA/Digital-Health-Applications/_node.html; 4. https://www.nice.org.uk/what-nice-does/digital-health/evidence-standards-framework-esf-for-digital-health-technologies; 5. Fassbender A et al. Therapeutics and Clinical Risk Management 2024;20:939–54

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