European Reimbursement Process Overview of Digital Medical Devices

HPR222

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BACKGROUND

The European market has seen a significant increase in CE-marked digital medical devices (DMDs), offering substantial benefits through mobile health, telehealth, telemedicine, wearable devices, and AI-based Software as a Medical Devices (SaMD). However, despite regulatory advances and a few prominent examples of Digital Therapeutics (DTx) reimbursement, market access remains delayed by inadequate reimbursement pathways for these technologies.

OBJECTIVES

Our research reviews reimbursement modalities for AI-based SaMD, E-health, and other DMDs, aiming to:

1. identify dedicated reimbursement paths for these digital technologies,
2. determine if general medical device reimbursement routes or innovation funding can accommodate digital technologies.

The research includes nine European countries: United Kingdom, Germany, Spain, Italy, France, Sweden, Poland, Croatia, and The Netherlands.

METHODS

We investigated the literature, including country-specific publications, official Health Authorities' websites and conducted expert interviews.

Type of DMDs considered	
Digital Health Technology (DHT)	▪ Mobile health ▪ Telehealth ▪ Wearable device ▪ Health information
Software as a medical device (SaMD)	▪ Web-based application ▪ (Smartphone) Application
Digital Therapeutics (DTx)	▪ Therapeutic intervention driven by software to prevent, manage or treat a medical disorder or disease

RESULTS

	UK	Sweden	France	Netherlands	Germany	Poland	Spain	Italy	Croatia
AI Reimb	Yes	No	Not covering HCP*- use AI DMD	Devices not routinely evaluated	No	No But in development	Methods Framework, not binding	No	No
Digital Health Reimb	Yes	No - Quality seal process for DMD	Yes - Patient-use apps, telemonitoring, connected devices	Insurer evaluations telehealth mobile apps	Yes-Patient use DTx apps; some telemonitoring	No But in development	Methodology from Cataluña but no process	No	No Pilot funding
Connected devices Reimb	Yes	No	Yes	Devices are not routinely evaluated	No	No	Plan progress	No	No
General Reimb	Yes - all programs can accommodate DMD/AI	Yes	Not for HCP-use	Few processes	Initiated by stakeholders	Initiated by HCP or stakeholders	No	Potentially applicable to AI	No
Innovation Reimb	Yes - specific for AI or appropriate for DMDs	Yes - mostly specific project calls	Yes	Yes - initiated by insurer-provider partnership	Yes - May not suite all types of AI DMDs	No	No	No	No

Table 1. Reimbursement overview for Digital Medical Device in 9 European Countries
* HCP: Healthcare professional

Our research finds significant disparities in the implementation of reimbursement pathways for digital health technologies across Europe. The UK exhibits the most comprehensive approach, whereas France and Germany have dedicated pathways with limited scopes (patient-use DMD and tele-monitoring in France; "DIGA" apps in Germany). Reimbursement for AI-based technologies is still unclear in these countries. Sweden and the Netherlands focus on remote care with no specific reimbursement routes, while Spain and Italy lack structured pathways despite having DMD evaluation frameworks. Poland shows efforts in progress but faces uncertainties, while in Croatia, there is no clear access to reimbursement for DMDs.

Process	Description	Initiation	Time from request (years) 0,5 1 1 ½ 2 2 ½ 3 3½
Diagnostic Assessment Program (DAP)	**General path, adapted for AI**	**Industry**	~13 months
Small scale experimentation	**Temporary funding**	Provider & insurer	8 weeks
Innovation & AI funding (AIDA)		Center/provider **+ Industry**	Calls twice per year
Nationally Managed Introduction	**General path**	MDT Council, Regions	Not fixed. Recent products: 2 years
Creation of a new medical procedure code		Health insurance, medical societies, **Industry**	Once a year, 2-5 years
Method Assessment (§ 135 SGB V)		Medical society, health insurance, evaluation body	2-5 years, no fixed timelines
Programma Nazionale di HTA dei Dispositivi Medici (PNHTADM)		**Industry**	6 months; Further no fixed timelines
Evaluation of healthcare services to be admitted to the "guaranteed benefit"		KOLs, scientific societies, patient organizations; rare for devices	No fixed timelines
Hospital/regional purchasing		Clinician/department	Once a year, no fixed timelines
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No HTA process for treatment / diagnostic devices; **local negotiations**			

Table 2. Timeline of most adapted procedure for AI-based SaMD reimbursement and funding

CONCLUSIONS

DMDs still **lack clear reimbursement measures** for timely market access and effective integration. For patient apps and remote care there are clearer reimbursement paths in some markets, but **in most countries, there are no processes for AI-based SaMD**.

DISCUSSION

Need for further development and harmonization: Reevaluating funding models to ensure equitable access to digital medical innovations across Europe.

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