

# Current Healthcare Policy and Environmental Status of Digital Health Medical Devices in South Korea

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## Background / Objectives

- COVID 19 and increasing unmet needs of health technology had accelerated an adoption of digital health globally and the major categories are mobile-health, health information technology, wearable health, telehealth, and telemedicine, and personalized medicine<sup>1</sup>. Digital health interventions have various benefits on clinical efficacy, quality of care and reducing healthcare costs.
- In many countries including United States, England, Germany, government had been developed regulations to enhance rapid market access of digital health medical devices.
- The objective of the study is to identify new reimbursement policy trend and current market access status of digital health in South Korea.

## Methods

- Main focused area were official notifications and guidelines announced from national bodies in Korea, including MOHW, MFDS, HIRA, NECA, NHIS. Policy tasks presented by Yoon Suk Yeol Administration were also reviewed to capture current political strategies of digital health in South Korea.
- In addition, research articles published by governmental institutions and academic industries were searched selectively to review current trends of digital health.

## Results

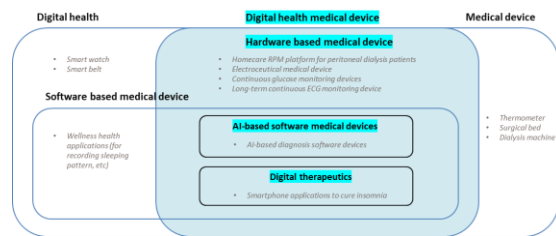
### Definition of Digital Health

- 'Digital health' is used by combining digital technologies such as Data, Networks, and Artificial Intelligence (D.N.A) in the field of healthcare.<sup>7</sup>
- 'Digital health medical device' is a medical device or software product with information and communication and mobile technology (ICT), mobile medical apps, U-Healthcare medical devices, artificial intelligence (AI), and software-oriented products with virtual and augmented (VR-AR) reality technology.<sup>8</sup>
- 'Digital therapeutics (DTx)' is a software as a Medical Device (SaMD) that provides evidence-based therapeutic intervention to patients for prevention, control and treatment of medical disorders and/or diseases.<sup>9</sup>

### Category of Digital Health

- 'Digital health medical device' is divided into 2 categories, 'hardware based medical device' and 'software based medical devices'. Hardware based medical device includes homecare RPM (Remote Patient Monitoring) platform connected to specific machines or electroceutical medical devices. 'Software based medical device' includes 'digital therapeutics' and 'AI-based software medical devices'.

Figure 1. Category of Digital Health<sup>10</sup>



## Value of Digital Health

- Digital health solutions can address some of the key challenges such as inequities and socioeconomic burdens in the healthcare sector. They can offer a means to overcome inequities and help healthcare service to reach rural communities and underserved populations which had no access to essential care. In addition, the intervention of digital health can shift the concept of healthcare system from curative to preventative, which can reduce healthcare costs.<sup>11</sup>
- Healthcare providers can use digital health solutions to monitor patients remotely to better efficiently track patient outcomes to help improve patient adherence, resulting fast recoveries and preventing further diseases. Furthermore, it is essential to enhance quality of care and empower patients to engage actively in managing their health, which leads to better patient-centered and personalized care.<sup>12</sup>
- Digital health solutions can improve the way care is delivered, helping process flows and diagnosis within hospitals. In addition, the adoption of digital health records improves its interoperability and efficiency by using aggregated data.<sup>14</sup>

### Digital Health Policy Trend in South Korea



- In Aug 2020, MFDS issued a guidance for review and approval of digital therapeutics.<sup>9</sup> The guideline includes definition, criteria, and examples of digital therapeutics and how to prepare for review and approval of digital therapeutics. Currently, MFDS is gradually developing guidance on safety, performance evaluation, and clinical trial design of digital therapeutics for each disease such as insomnia, depressive disorders from 2020. In Feb 2023, the first digital therapeutics 'Somzz', smartphone application to care insomnia, has been approved and more than 25 digital therapeutics are undergoing clinical trials in Korea.<sup>13</sup>
- In Feb 2022, NECA expanded the scope and period of nHTA (new Health Technology Assessment) grace period, which is a system to introduce in market for 2 years and extra period of nHTA assessment as non-reimbursement for earlier use at clinical environment.<sup>16</sup> In Apr 2023, 4 of digital health medical devices including AI-based software devices, are approved as grace-period of nHTA and cardiovascular risk prediction software with AI software for retinal imaging will be approved in May 2023.
- In May 2022, Yoon Suk-Yeol administration announced new initiatives to boost up bio-digital health in Korea as its 25th policy tasks. To achieve the goal of creating new digital market and vitalizing biohealth, the government has established a 'biohealth new market creation strategy' in 2023. It includes extension of assessment HTA grace-period, expansion categories of integrated assessment system, reimbursement guideline development for digital therapeutics and introduction of telemedicine especially for clinics.<sup>17</sup>
- In Oct 2022, MOHW had issued integrated assessment pathway for innovative medical devices to accelerate market access.<sup>14</sup> Before this announcement, there was about 25 innovative medical devices approved by MFDS, but after the approval, it took 390 days to introduce in market because they should be reviewed by HIRA and NECA separately. Also, most of them was reviewed as 'previous technology', not a 'new' technology by HIRA so there was a limitation to get reimbursed by government. To accelerate market access of innovative medical devices, MOHW issued this integrated pathway, which shortened review period to 80 days and after approval, devices can be used as non-reimbursement for 3 to 5 years in market. Medical devices with AI software-Bigdata technology or digital-wearable technology can be applied to the pathway. In Dec 2022, 2 digital therapeutics for treatment of insomnia and 1 electroceutical medical device for major depressive disorders was approved by this integrated pathway and introduced as non-reimbursement use.<sup>15</sup>

## Market Access Status of Digital Health in South Korea

- With policy development in South Korea, digital health medical devices have been introduced as non-reimbursement by utilizing grace period of nHTA pathway and innovative medical devices integrated assessment pathway from 2022.
- In addition, there is remote patient monitoring (RPM) reimbursement service fee. Continuous glucose monitoring devices have been reimbursed for type 1 diabetes patients by NHIS since January 2019. Homecare RPM service for peritoneal dialysis patients with cloud platform (Sharesource) has been reimbursed since December 2019, and long-term continuous ECG monitoring service fee for wearable ECG monitoring devices became reimbursement since February 2022.

Table 1. market access status of digital health in South Korea

Reimbursement pathway	Reimbursement status	Product name (Manufacturer)	Objective	Category	Reimbursement pathway	Reimbursement status	Product (Manufacturer) name	Objective	Category
Grace period pathway of nHTA	Non-reimbursement use ('22.06 - '24.05)	MINDD STIM( Ybrain)	To treat with major depressive disorders using transcranial direct stimulation	Hardware based digital health medical device	National Health Insurance Service caring fee	Reimbursement (Since 2019)	Freestyle Libre (Abbot), etc.	To manage glucose level of diabetes mellitus patients by continuous glucose monitoring	Hardware based digital health medical device
	Non-reimbursement use ('22.08 - '24.07)	DeepCARS (Vuno)	To monitor the risk of cardiac arrest within 24 hours	AI-based medical device software					
	Non-reimbursement use ('22.08 - '24.07)	iSyncBrain MCI Classifier (iSyncBrain)	To diagnosis cognitive impairment	AI-based medical device software					
	Non-reimbursement use ('23.03 - '25.02)	AITRICS-VC (AITRICS)	To predict risk of sepsis or death	AI-based medical device software					
Integrated assessment pathway for innovative medical devices	Non-reimbursement for 3 to 5 years	Somzz (Aimmed)	To treat insomnia cognitive behavior applying standard treatment protocol as an algorithm to mobile apps	Digital therapeutics (smartphone applications)	Remote monitoring service fee generation	Reimbursement within PD pilot project (Since 2019)	Sharesource (Baxter)	To provide homecare RPM platform for PD (Peritoneal Dialysis) patients to prevent PD related complications and enhance patient satisfaction	Hardware based digital health medical device
		WELT-1 (Welt)							
		JBS-01K (JLK)	To diagnosis cerebral infarction	AI-based medical device software					
	Reimbursement with 80% co-payment (Since 2022)					Atpatch (ATSens), etc.	To diagnosis cardiac diseases by RPM of ECG	Hardware based digital health medical device	

## Conclusion / Discussion

- Although Korean government has been developed guidelines for digital health actively, only few products had been reimbursed. To introduce new technologies for improved patient centric treatment, novel value-based assessment, and new pricing guideline for 'digital health medical devices' are required. HIRA is trying to establish reimbursement guidelines for digital therapeutics until 2023, but reimbursement guidelines for whole 'digital health medical devices', not limited to digital therapeutics, is necessary. Especially specific guidelines for remote patient monitoring devices should be developed to provide opportunities for better manage and track chronic disease patient's conditions.
- Many countries have already reorganized their healthcare system to promote digital healthcare. For example, in France, RPM and prescription remote transmission service by Diabetes Mellitus management application (Voluntis<sup>®</sup>) is covered by ETAPES national reimbursement as more than 300 EUR per 6 months. In South Korea, it is also vital to actively respond to social problems such as aging society by adopting digital healthcare.
- In Korea, since the payment system is based on fee for service, only reimbursement could induce the medical utilization. However, the payment system includes areas of diagnosis and treatment, except for areas of disease prevention and follow-up management. Most digital health medical devices aim to prevent disease, manage care, and improve the accuracy and convenience of existing medical practices, so that if existing medical practices cannot be replaced by digital health, it is difficult to prove their effectiveness compared to existing practices to get separate reimbursement. Only when the reimbursement fee is applied, it can be actively used in the clinical field, and clinical data can be secured naturally.
- Currently, pharmaceutical and device companies are developing 'digital health medical devices' including smartphone applications for RPM, which is not included in digital therapeutics but vital to manage patient's outcome. However, it is harsh to be introduced in market well due to lack of government guidelines and supports. The government should establish a virtuous cycle structure by developing novel assessment system for 'digital health medical device' and applying the reimbursement fee.

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