Digital Healthcare

Regulatory Environment in Korea

June 29, 2021

KIM & CHANG

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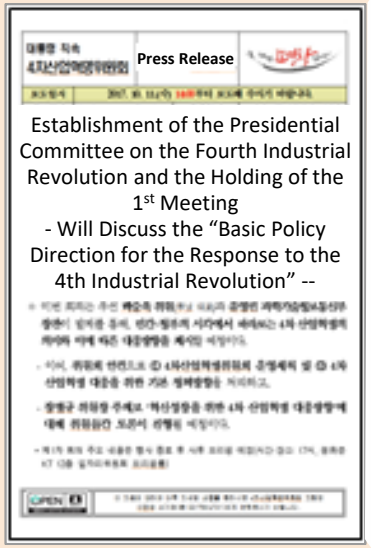
I. Korean Government's Effort in Digital Health

Effort to Relax Regulations: MOSF's Investment Invigoration Plan (2017)

Presidential Committee
on the Fourth Industrial Revolution


Press Release

Establishment of the Presidential Committee on the Fourth Industrial Revolution and the Holding of the 1st Meeting
- Will Discuss the "Basic Policy Direction for the Response to the 4th Industrial Revolution" --

III. Policy Direction and Key Directives

② **[Smarter Public Services]** Address social issues, improve quality of people's lives through convenient and safe public services and create leading market for innovative growth

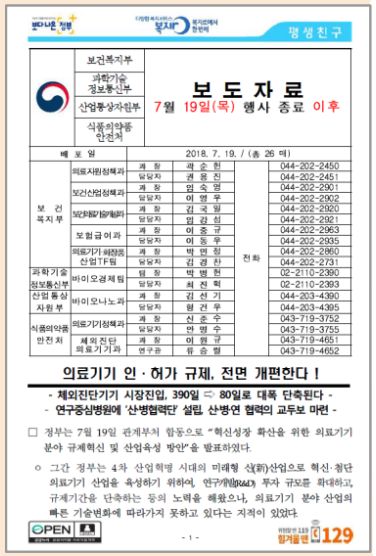
- o Identifies Health as one of the impacted area and states: "Expansion of customized precision medicine, ***commercialization of AI medical robots***, development of innovative ***new AI-based medicines***, etc."

③ **[Pro-Innovation Regulations] Redesign regulatory system** by introducing ***regulatory sandbox*** to facilitate soft landing of ***new technologies/services*** in the market and **exempting individual regulations** in time for commercialization

Source: Press Release by the Presidential Committee on the Fourth Industrial Revolution (Business Plan dated 2017. 10. 11.)

Efforts to Relax Regulations: The President and the Korean Government Ministry Announces Joint Regulation Reform (2018)

보건복지부
과학기술정보통신부
산업통상자원부
식품의약품안전처



보 도 자 료

7월 19일(목) 행사 종료 이후

의료기기 인·허가 규제, 전면 개편한다 !

- 체외진단기기 시장진입, 390일 ⇨ 80일로 대폭 단축된다 -
- 연구중심병원에 '산병협력단' 설립, 산병연 협력의 교두보 마련 -

I. Implementation of Comprehensive and Negative Regulation

Medical devices are highly regulated and it will pass through various regulatory processes (at least 520 days)

Process	Approval of Medical Device	Assess payment assistance subjects	New Technology Assessment	Insurance Payment Registration
Agency	Ministry of Food and Safety	Health Insurance Review and Evaluation Service	Ministry of Health and Welfare – New Medical Technology Assessment Committee	Health Insurance Review & Assessment Service
Contents of Examination	Product safety and performance	Evaluate whether it qualifies as convalesce or payment assistance programs	Side effects, death rate, and efficacy of medical treatment	Evaluation on payment suitability and economic feasibility
Duration	80 Days	30 days (In-depth analysis 60 days)	280 days	100 days

The current Korean government intends to reform regulations for medical devices with little safety risks to allow **pre-market post-product evaluation** (known as the Comprehensive Negative Regulation).

Source: Government's Joint Press Release (2018.07.19. Significant Medical Device Regulation Reform 0

Government Involvement in Digital Health

- Guidelines Published by the MFDS and the US FDA

	2013	2015	2016	2017	2018~2019	2020~2021
Korea	• Safety Control Guidelines for **Mobile Medical Applications** (2013.12.26)	• Classification Standards for **Medical Devices and Personal Wellness Products** (2015.7.10)	• Itemized License/Review Guidelines for **U-Healthcare Medical Devices** (2016.5) • Performance Evaluation Guidelines for **Next-Generation Sequencing**-based In vitro Diagnostic Medical Devices (2016.7) • Safety/Performance Testing Guidelines for Biodegradable Scaffolds for Skin Regeneration Produced by **3D Printers** (2016.12)	• License/Review Guidelines for Medical Devices Applying **Big Data and AI Technology** (2017.11) • License/Review Guidelines for **Rehabilitation Robots** (2017.11) • **Cybersecurity License/Review** Guidelines for Medical Devices (Tentative) (2017.11)	• Guideline and Case Study on **Non-Medical Services** (2019.05) • Guidelines on **Application of Real World Evidence on Medical Devices** (2019.03) • Guideline on **Approval of Medical Devices Utilizing Virtual Reality (V/R) and Augmented Reality (A/R)** (2018.07) • Guidelines on License and Review of Cybersecurity of Medical Devices (2019. 11)	• Guidelines on License and Review of Digital Therapeutic Devices (2020. 08) • Guidelines on Certification Procedures and Standards of Companies Developing Software of Breakthrough Medical Devices (* Similar to the Pre-Certification system in the US) (2021. 01)
US	• Content of **Premarket** submissions for management of **cybersecurity in medical device** (2014.10)	• Medical Device Data Systems, **Medical Image Storage Device** and Medical Image Communications (2015.2) *** Cloud Service Guidelines** · Guidance for **Mobile Medical Application** (2015.2)	• **General Wellness** : Policy for low risk Device (2016.07) • **Postmarket** Management of **Cybersecurity in medical device** (2016.12)	• Draft Guidance of **Digital Health Innovation Action** Plan (PDF) (2017) • Developing the **Digital Health Software Precertification Pilot Program ("Pre-Cert")** (2017.09) • Guidance for **Software As a Medical Device** (2017.12) • Draft Guidance for **Clinical and Patient Decision Support Software** (2017.12) • *** AI Technology Guidelines** • **Change to Existing Medical Software Policies** (2017.12)	• Issuing guidance to modernize FDA's policies, including: • The 2019 **Clinical Decision Support Software**" draft guidance (2019.09) • **Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act** Final Guidance (2019.09) • **Policy for Device Software Functions and Mobile Medical Applications** Final Guidance (2019.09) • **General Wellness: Policy for Low Risk Devices** Final Guidance (2019.09)	• Multiple Function Device products : Policy and Considerations

Various Stakeholders the Ministry of Health and Welfare ("MOHW") and Others (2017~2021)

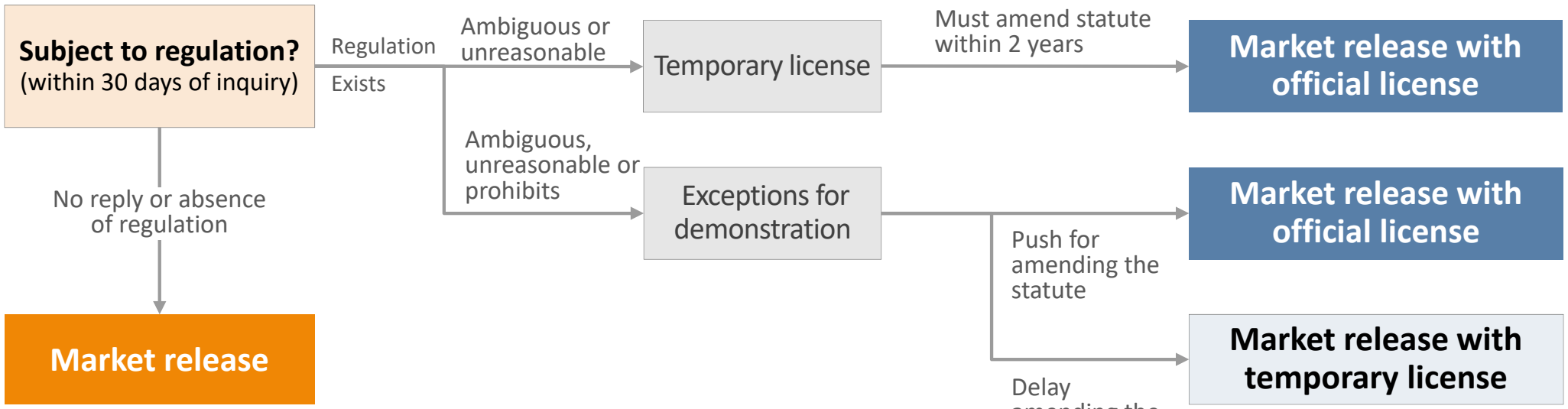
2018.07	Guidelines for measures to make personal information non-identifiable: Criteria, support and management to make personal information non-identifiable and
2019.05	Guidelines for Non-Medical Health Care Management Services and Casebook (1st)
2020.12	Guidelines for Development and Sale of Health Promotion Type Insurance Products
2019.12	Assessment Guidelines for Providing Medical Care Benefits to Cutting-edge Medical Technologies: AI-based Medical Technology (Image Medical Science) & 3D Printing Using Medical Technology
2020.12	Assessment Guidelines for Providing Medical Care Benefits to Cutting-edge Medical Technologies: AI-based Medical Technology (Pathology)
2021.01	2021 Guidelines for Use of Health and Medical Data

Application: Introduction of Regulatory Sandbox (enforced in Jan. 2019)

Regulatory Sandbox?

Redesign regulatory system by introducing ***regulatory sandbox*** to facilitate soft landing of new ***technologies/services i***n the market and exempting individual regulations in time for commercialization

Procedures of the Regulatory Sandbox System

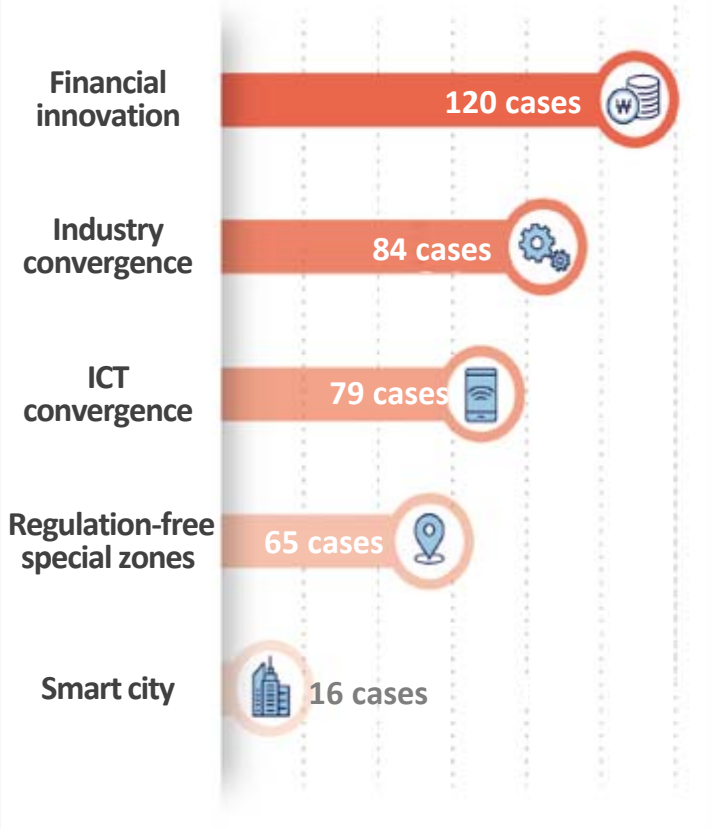


❖ Except for prohibited or without license cases

Data : Office for Government Policy Coordination

Application: Current Status of Projects Utilizing Regulatory Sandbox (Nov. 2020)

1 Approved projects: 364 cases



HUINNO	Heart disease management service using watch-type electrocardiogram device
	Allowed as an exception even though there are ambiguity in managing patients using wearable devices (2019)
Olive Healthcare	Online brokerage service between clinical trials and those wishing to participate
	No regulation: the Ministry of Food and Safety's notice clarified the online recruiting permit
LG Electronics SNU Hospital	Home care algorithm development and guide service for hospital visits
	No regulations: collection and study of arrhythmia measuring SW data does not constitute clinical trial
neofect	Home rehabilitation training devices and services
	Allowed as an exception despite prohibition of telemedicine and the obligation to store medical records (2019)
IT EY CNC	Risk sensing service using vital signs
	Allowed as an exception despite the obligation to assess suitability of mobile devices used for a specific purpose
macrogen	App-based tailored health promotion service based on DTC genome analysis
	Permitted as an exception to add 13 diseases to genetic tests directly performed by non-medical institutions
RS Care Service	Electric auxiliary kit for manual wheelchairs
	Allowed as an exception without certification as medical devices
Neo LFN	Sub-kit of auxiliary power unit for wheelchairs
	Allowed as an exception without certification as medical devices

II. Current Issues in Korea Related to Digital Health

Current Issues in Korea Related to Digital Health

Stage 1 → Stage 2 → Stage 3 → Stage 4

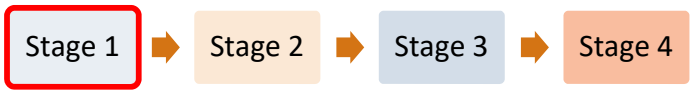
Medical Devices Industry Act	**Act on the Fostering Medical Devices Industry and the Supporting Breakthrough Medical Devices (Stage 1)** • What is Breakthrough Medical Device Company and Breakthrough Medical Device
HTA	**Health Technology Assessment (Stage 3)** • New Technology Assessment • Breakthrough Technology Assessment
HIRA	**Health Insurance Review and Assessment Service (Stage 2/4)** • Reimbursement issue concerning digital health

Overview Process Relevant for Medical Device

Process	*Stage 1*	*Stage 2*	*Stage 3*	*Stage 4*
	Approval of Medical device	Access Payment Assistances	New Technology Assessment	Insurance Payment Registration
Agency	MFDS	HIRA	MOHW – New Medical Technology Assessment Committee	HIRA
Contents of Examination	Product safety and performance	Evaluate whether it qualifies as convalesce or payment assistance programs	Side effects, death rate, and efficacy of medical treatment	Evaluation on payment suitability and economic feasibility
Duration	80 days	30 days (in depth 60 days)	280 days	100 days

Regulatory Sandbox

Medical Devices Industry Act



Overview on the Medical Devices Industry Act

Stage 1 → Stage 2 → Stage 3 → Stage 4

"Breakthrough Medical Device Company": certification

- Certification is valid for 3 years and extension is possible through re-assessment every 3 years.
- Benefits: Certified companies are able to preferentially participate in (1) state R&D projects, be subject to tax reduction/exemption, granted an exception concerning construction of research facilities, and exempted from development charge, etc. for research facilities, etc.

See the Medical Devices Industry Act (enacted in May 2019 and enforced in June 2020)

Classification and Certification of Breakthrough Medical Device Companies (tentative)

Certification type		Subject of certification	Certification method
Leading company	Company with KRW 50 billion or more	Ratio of R&D investment to annual sales of medical devices: 6/100	A committee's deliberation is required based on the certification criteria set forth in Article 10 of the Medical Devices Industry Act and Article 14 of the Enforcement Decree (Tentative).
Start-up company	Company with lower than KRW 50 billion	Ratio of R&D investment to annual sales of medical devices: 8/100 or KRW 3 billion annually	
	Company designated for breakthrough medical devices	Medical devices company engaged in R&D and production of breakthrough medical devices designated as per Article 21 of the Medical Devices Industry Act	

* Companies engaged in R&D and production of breakthrough medical devices may be designated as Breakthrough Medical Device Companies irrespective of their scale of R&D investment (Article 2, subparagraph 3, Item C of the Act)

Overview on the Medical Devices Industry Act: Breakthrough Medical Device Company

Stage 1 → Stage 2 → Stage 3 → Stage 4

Certification procedures for obtaining "Breakthrough Medical Device Company" Designation

Announce a notice of application for certification as Breakthrough Medical Device Company	Receive applications	Review documents	Evaluate companies	Announce certified companies
MOHW	Comprehensive Support Center ("Support Center") - Korea Health Industry Development Institute	Support Center	Industry Fostering Committee	MOHW

Evaluation items	Key description for evaluation
Excellence of input resources (30)	• R&D investment records: R&D investment ratio (5) • Current status and composition of research personnel: Ratio of research personnel (1) • Current status of R&D and production facilities: Whether to have overseas GMP certification, etc. (1)
Innovativeness of R&D activities (30)	• R&D vision and mid & long-term driving strategy • Partnership and cooperation activities at home and abroad • Medical device R&D activities and performances: Publication of papers (3)
Excellence of R&D outcomes (30)	• Patent and technology transfer and commercialization performances: leading type (2), start-up type (3) • Overseas market entry performances: leading type (2), start-up type (3) • Excellent medical device development and distribution performances
CSR (10)	• CRS, ethics and transparent business management
Total (100)	

Overview on the Medical Devices Industry Act: Breakthrough Medical Device Company *(as of Nov. 2020)*

Breakthrough: leading type (>KRW 500 B)	
Company	Key Area
LUTRONIC	Laser therapy apparatus
SAMSUNG MEDISON	Ultrasonic scanning apparatus
Seegene	In vitro diagnostic medical device
i-SENS	Blood glucose monitoring device
OSSTEM IMPLANT	Dental implant
InBody	Body fat analyzer/blood pressure gauge
SIEMENS Healthineers	Ultrasonic scanning apparatus

Breakthrough: Start-up type (KRW <500 B)	
Company	Key Area
Koh Young Technology	Robotic surgery instrument
NIBEC	Dental bone blocks
NEXTBIOMEDICAL	Stent/ hemostatic items
Novomics	In vitro diagnostic medical device
DAWON MEDAX	Neutron cancer targeted therapy apparatus
Ray	Dental imaging diagnosis device
Lunit	AI diagnosis support S/W
VUNO	AI diagnosis support S/W
INFINITT Healthcare	Medical image software
GENCURIX	In vitro diagnostic medical device
MEDIANA	Vital signs monitors

Overview on the Medical Devices Industry Act: Breakthrough Medical Device

Stage 1 ➡ Stage 2 ➡ Stage 3 ➡ Stage 4

Newly established definition of 'breakthrough medical device'

- What is a "Breakthrough Medical Devices"?
- Medical devices which **have significantly improved or are expected to significantly improve safety and effectiveness** compared to existing medical devices or treatments, by **applying cutting-edge technology in highly tech-intensive areas with fast innovation pace** such as information and communications, bio and robotic technologies, of the medical devices in Article 2(1) of the Medical Devices Act, and have been designated by the MFDS.

Efforts to promote breakthrough medical devices' entry to market

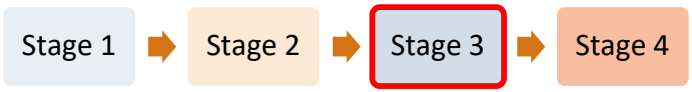
- Introduce a system of designating breakthrough medical device and phased/ priority examination (e.g., similar to the US.FDA Breakthrough Device Program)
- Introduce a system of certifying companies developing breakthrough SaMD (e.g., similar to the US.FDA Pre-Certification Program)
- Reduce the breakthrough software's scope of permitting change (e.g., similar to the US.FDA "Changes to Existing Medical Device Software Polices")
- Newly establish the criteria to manage clinical trials of breakthrough software (e.g., Good Clinical Practice)

Overview on the Medical Devices Industry Act: Breakthrough Medical Device (*as of Jan. 2021*)

No.	Company	Item	Product	Designation date
1	VUNO	Medical image diagnosis support software	VUNO Med - Fundus AI	July. 22, 2020
2	DAWON MEDAX	Therapeutic neutron irradiation equipment	A-BNCT	July. 22, 2020
3	heuron	Medical image diagnosis support software	mPDia	July. 28, 2020
4	SKIA	Medical navigation system	Mars-Breast	Aug. 3, 2020
5	Lunit	Medical image diagnosis support software	Lunit INSIGHT CXR	Sep. 18, 2020
6	VUNO	Visceral function tester	VUNO Med – DeepCARS	Sep. 22, 2020
7	Coreline Soft	Medical image diagnosis support software	AVIEW NeuroCAD	Nov. 17, 2020
8	Medi Whale	Cardiovascular risk assessment software	DrNoon for CVD	Dec. 24, 2020

Available at : https://www.mfds.go.kr [Information → News & Notice → Notice]

Health Technology Assessment & Breakthrough Technology Assessment



[HTA] Adopting New Process for Breakthrough Medical Technology

Stage 1 → Stage 2 → **Stage 3** → Stage 4

Apply for new medical technology evaluation
Submit a written opinion on the capability/ potential of the new medical technology

Evaluate whether the technology constitutes a breakthrough medical technology
If not, evaluate under the new medical technology

Who: a separate Breakthrough Medical Technology Deliberation Committee

Organize a sub-committee for assessment of safety and effectiveness

+

Organize a sub-committee for assessment of breakthrough medical technology

What: Assess the capability/potential of breakthrough medical technology

New medical technology assessment committee (final deliberation)

Consider: (1) safety and effectiveness and (2) capability/potential of the medical technology to determine whether it constitutes a Breakthrough Medical Technology

- **Pre-existing technology**
- **New medical technology**
- **Research-stage technology**
- **Breakthrough medical technology** (conditional new med)

[HTA]– Adopting New Process for Breakthrough Medical Technology

Stage 1 ➡ Stage 2 ➡ **Stage 3** ➡ Stage 4

Standards for Breakthrough Medical Technology

[Exhibit 1]

Category	Deliberation items	Matters to be reviewed upon deliberation
Technical attribute	Customized medical technology	Is this medical technology expected to enhance the medical output by providing customized diagnosis and treatment solutions based on individual patient's circumstance?
	Use of breakthrough or cutting-edge technology (device)	Does this medical technology use breakthrough/cutting-edge technology or device from a highly tech-intensive field with fast development? ※ E.g., 3d printing, robot, implantable device, virtual/augmented reality, Nano tech, AI, etc. and promising medical technology acknowledged by public institutions as new excellent technology ("NET"), etc. or activities exploring newly developed medical technology, etc.
Social attribute	Disease with high demand in society	Does this medical technology concern catastrophic diseases such as cancer, heart disease, cerebrovascular, or rare or incurable disease?
	Absence of alternative technology	Does this medical technology concern a disease which has no standard (comparative) treatment or pre-existing treatment recommendation guides available?
Medical attribute	Patient-centered technology	Is this medical technology expected to reduce patients' inconvenience by (i) lowering invasive level, (ii) shortening the time, and (iii) enhance patients' satisfaction by improving patients' adherence to treatment?
	Enhanced medical output	Is this medical technology expected to enhance the quality of medical practice and outcome by (i) increasing the accuracy of the diagnosis, (ii) operation success rate, and (iii) lowering mistakes, etc.?

[HTA] Adopting New Process to Determine Breakthrough Medical Technology

Stage 1 → Stage 2 → **Stage 3** → Stage 4

Examples of "Breakthrough Medical Technology" Designation for real world evidence – 3 cases in total (as of Jan. 2021)

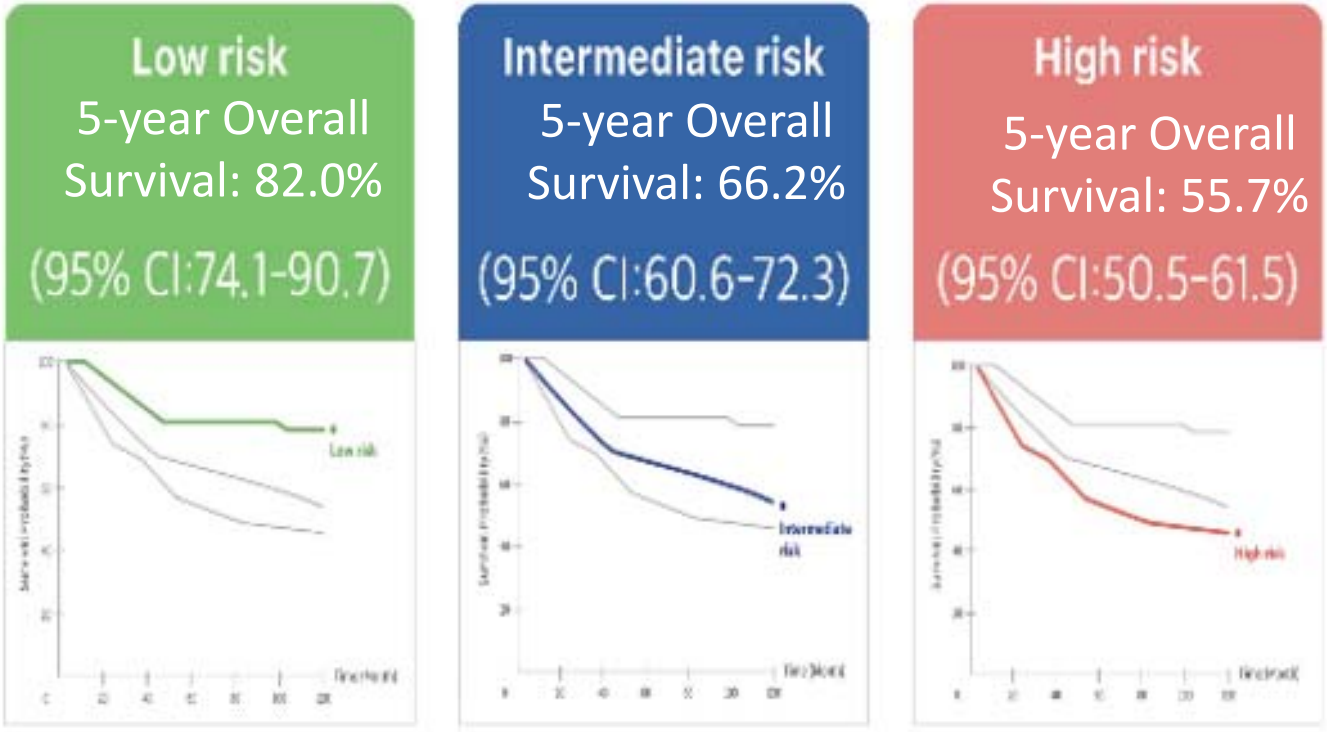
Genetic diagnostic test for predicting prognosis of stomach cancer (Nov. 2019)	***Purpose of use***	Provides prognosis on cancer patients' five-year survival rate
	Subject of use	Patients with 2~3-stage advanced stomach cancer
	Period of use	Nov. 1, 2019 ~ Oct. 31, 2024
Algorithm-based test for prognosis of early-stage breast cancer patient through gene expression (Dec. 2020)	***Purpose of use***	Provide prognosis information of the risk of metastasis to other organs in 10 years for early-stage breast cancer patients
	Subject of use	Female patients with early-stage breast cancer with HR+, HER2-, pN0
	Period of use	Dec. 1, 2020 ~ Nov. 30, 2025
Autologous peripheral blood stem cell therapy for acute myocardial infarction patients' cardiac tissue regeneration	***Purpose of use***	Regenerate cardiac tissue and improve myocardial function using peripheral blood stem cell
	Subject of use	Patients with degraded heart function who successfully received percutaneous coronary intervention after having an acute thrombotic occlusion
	Period of use	Dec. 1, 2020 ~ Nov. 30, 2025

Example

Novomic nProfiler® 1 – Stomach Cancer Assay

Test Results & Interpretation

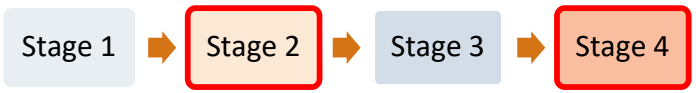
nProfiler® 1 Stomach Cancer Assay measures 9 gene-expression levels in stomach cancer tissue and classifies the prognosis using an algorithm. The assay analysis provides information on a patient's overall likelihood of **survival for the next 5 years** and classifies them into Low risk, Intermediate risk, or High risk groups based on their prognosis. The classifier system of nProfiler® 1 Stomach Cancer Assay was **cleared by the Ministry of Food and Drug Safety (MFDS, Approval No. 17-865) on November 10, 2017**.



Nov. 2019

The first Breakthrough Medical Technology

Reimbursement issue concerning digital health: Health Insurance Review and Assessment Service



[HIRA] Assessment Guidelines for Providing Medical Care Benefits to Cutting-edge Medical Technologies

Stage 1 → Stage 2 → Stage 3 → Stage 4

AI-based medical technology (Image Medical Science) – Dec. 2019

Guidelines by the Health Insurance Review and Evaluation Service – provide the criteria to determine 'existing technologies'

- AI-based medical imaging technology **provides minor/major diagnosis (auxiliary) information within the extent of the said test's general roles.**

"Examples of existing technologies" described in the guideline → existing payment (A to C1)

Category	Description of examples
A	A technology that may improve the process for HCP diagnosis
B	A technology that can detect boundary and description, etc. of suspected areas which are not visible to human eyes
C1	A technology that can identify suspected lesion areas and **makes a potential diagnosis**
C2*	Similar to existing technology but with **significantly improved accuracy that makes less mistakes than humans.**
D or E	Provide completely new information **beyond** the test's general function (use of biomarker) or **replaces** existing expensive medical services → **Subject to New Medical Technologies Assessment**

[HIRA] Assessment Guidelines for Providing Medical Care Benefits to Breakthrough Medical Technologies

Stage 1 → Stage 2 → Stage 3 → Stage 4

AI-based medical technology (pathology) – Dec. 2020

Guidelines by the Health Insurance Review and Evaluation Service – provide the criteria to determine 'existing technologies'

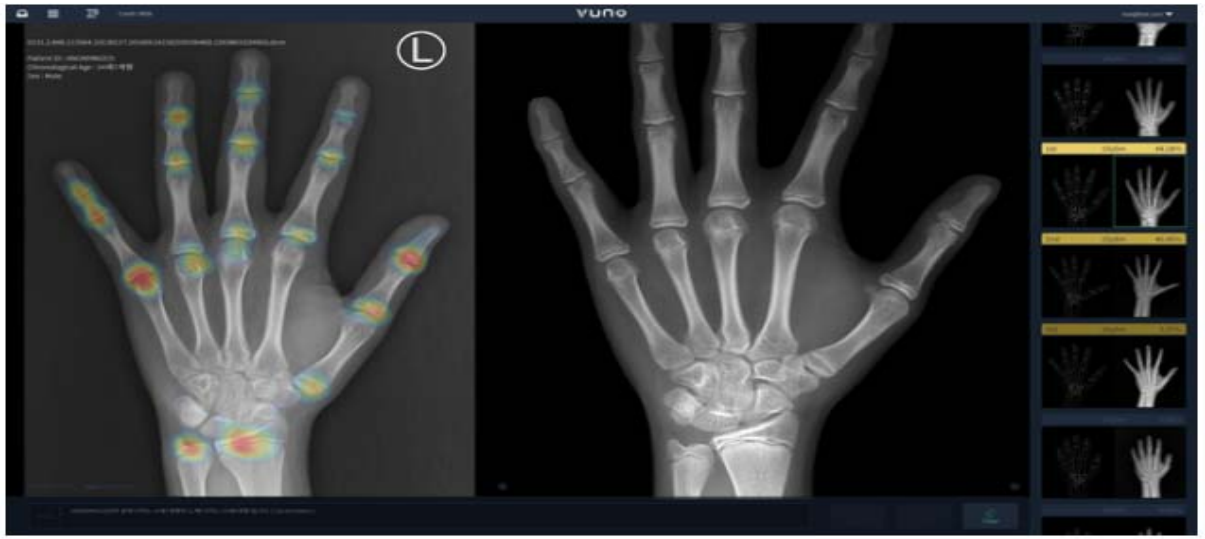
- AI-based analysis technology **provides major diagnosis (auxiliary) information within the extent of the said test's general roles.**

"Examples of existing technologies" described in the guideline → **existing payment (A to C1)**

Category	Description of Example
C1	A technology that **enhances the coincidence level** compared to the pre-existing diagnosis made using a microscope, etc. and **enhances the coincidence level** of reading outcomes among reading doctors.
C2*	A technology that **reduces the areas of difficulty in definite diagnosis of boundary,** as per the nature of the test for definite diagnosis, **thereby reducing the need for additional tests.**
C2*	A technology that clearly **enhances diagnosis accuracy** and diagnostic ability.
D or E	Provides completely new information **beyond** the test's general function (use of biomarker) or **replaces** existing expensive medical services → **Subject to New Medical Technologies Assessment**

Example

Vuno Med®- BoneAge (the first AI-based medical device in Korea)



May 2018

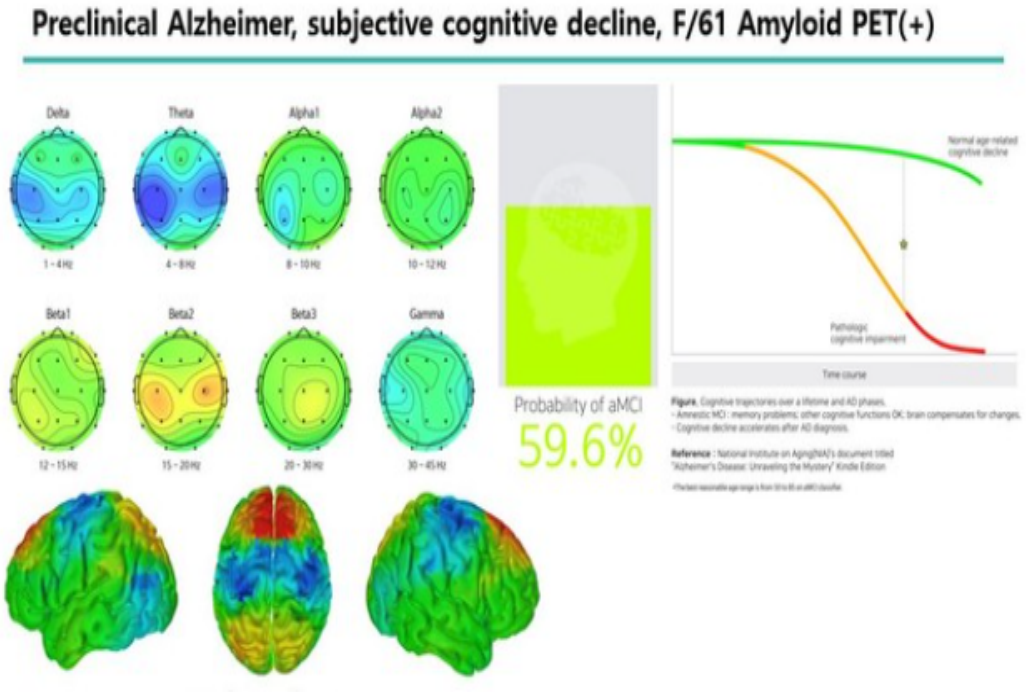
- Assessed as an existing technology (Fees for simple diagnosis based on radiologic imaging, C-165 Bone age)

New medical technology assessment (SaMD based on AI Tech) in progress – Integrated review

Filing No.	Technology Category	Title	Filing Date	Completion Date	Progress	Bibliographic search formula and whether the submitted literature is included	Criteria/Ground for Evaluation
2021024	Other Examination	AI-based diagnosis of prostate cancer	Feb. 23, 2021		In progress		
2020109	Other Examination	AI-based diagnosis of cerebral aneurysm	Sep. 7, 2020		In progress		
2020075	Other Examination	AI-based auxiliary software for diagnosing mild cognitive disorder	July 3, 2020	Feb. 5, 2021	**Completed**	View More	View More

Example

VS



Category E	A technology that **replaces the expensive existing medical service** by adopting AI-based medical imaging technology	• Assesses liver cirrhosis levels by CT scanning the liver instead of using MR elastography	Subject to new medical technology assessment

July 2020

- Assessed as a "New Medical Technology"
- iSyncBrain®
- Software that analyzes brainwaves for early detection of amnestic mild cognitive impairment (aMCI) known as a precursor to Alzheimer's disease

[HIRA] Criteria to determine whether a technology assessed as a new medical technology can be covered by insurance

Stage 1 → Stage 2 → Stage 3 → Stage 4

[Table 4] AI-based medical technology (Image Medical Science)

Category	Details	Included Example	Remark
Level 1	• A technology than can create the effect of generating additional profit or reducing indirect costs mainly for medical institutions by **increasing the efficiency of medical treatment**	Category A Category B	Separate compensation not applicable
Level 2	• A technology that shows a **similar lev**el of diagnostic ability to that of the existing service • A technology that significantly improves certain parts of the diagnostic ability of the existing service but shows a **similar level of diagnostic ability in general**	Category C1 Category C2	Separate compensation not applicable
Level 3	• A technology that **substantially improves** diagnostic ability compared to the existing service • A technology that generates **new** diagnostic value or has a treatment effect	Category C2 Category D	Separate compensation considered
Level 4	• Where **cost efficiency** has been proven in addition to Level 3 attributes	Category C2 Category D Category E	Separate compensation considered

[Table 4] AI-based medical technology (Pathology)

Category	Details	Included Example	Remark
Level 1	• A technology that can generate additional profit or reduce indirect costs for medical institutions by **increasing the efficiency of medical imaging interpretation**	Category A Category B	Separate compensation not applicable
Level 2	• A technology that shows a **similar level of diagnostic ability** to that of the existing service • A technology that significantly improves certain parts of the diagnostic ability of the existing service but shows **a similar level of diagnostic ability in general**	Category C1	Separate compensation not applicable
Level 3	• A technology that clearly improves the diagnostic ability compared to the existing service • A technology that generates new diagnostic value or provides new information beyond the scope of its general role	Category C2 Category D	Separate compensation considered
Level 4	• Where cost efficiency has been proven in addition to Level 3 attributes	Category C2 Category D Category E	Separate compensation considered

III. Other Issues Related to Digital Health

1. Telemedicine

Is it a Medical Service?

Only healthcare professionals (HCPs) are permitted to undertake medical services (Article 27 of MSA)

Considerations

- "Medical services" not defined in MSA
- The Supreme Court of Korea defined "medical services" as "acts of preventing or treating illnesses" and "acts that may cause public health related risks unless conducted by HCPs"

Issues

- Counseling (Genetic- DTC Counseling)
- Diet/exercise guidance
- Provision of objective information
- Individualized data analysis

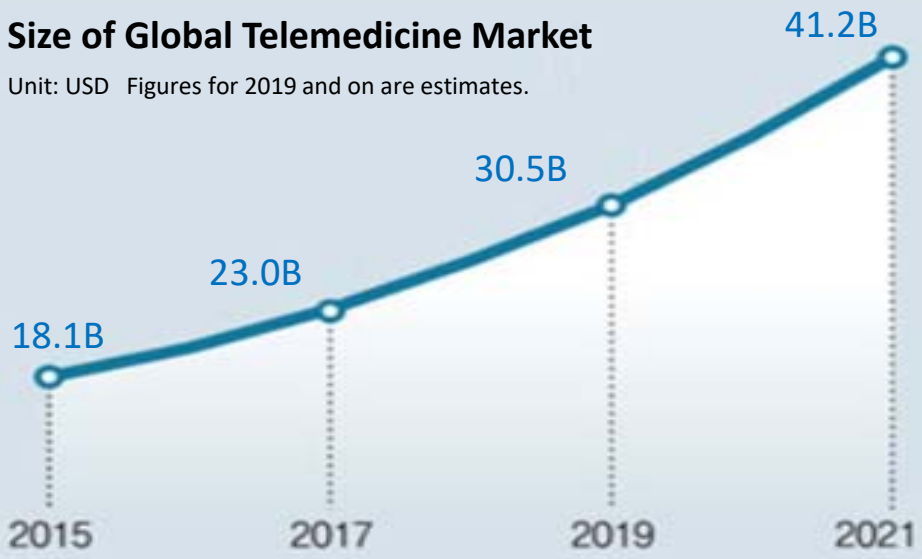
Global Telemedicine Market Trend

Obtaining Approval for Remote Medical Device … Practically Useless because of "Too Strict Regulations"

Edited by: Journalists Seong-Min Park and Ji-Won Sa Edited on: June 14, 2019 03:00 Updated on: June 13, 2019 03:00

Size of Global Telemedicine Market

Unit: USD Figures for 2019 and on are estimates.



Source: a market research firm called 'Statista'

Telemedicine Industry in Major Foreign Countries

Country	Details
U.S.	Permitted telemedicine services since **the 1990s**
France	Amended the relevant law in **2009** to allow claiming consultation/diagnosis/drugs
U.K.	Monitoring patients suffering chronic diseases, etc. through telemedicine services since **2008**
China	Introduced telemedicine services in **2016;** Size of the online medical service market amounts to KRW 4 trillion a year

Source: Korea Institute for Health and Social Affairs, etc.

Markets for telemedicine are growing rapidly in other countries

Conflicting Views on Telemedicine

Pros

- Can resolve issues faced by medically underserved areas such as remote areas, and improves convenience
- Can ***enable efficient management*** of ***chronic diseases*** in the upcoming era of population ageing
- Gives an opportunity to enter overseas markets and creates added-value in the medical service industry

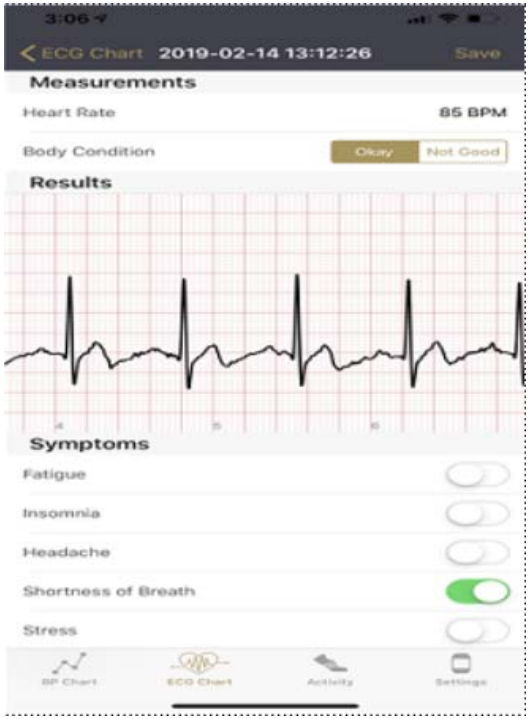
Cons

- Higher likelihood of misdiagnosis infringes the right to health
- Potential breakdown of healthcare system in local hospitals
- Not suitable for Korea where citizens have easy access to good healthcare services
- Difficult to determine the liable party if a medical incident occurs

None of the bills to amend the Medical Service Act to allow remote medical services that have been proposed to the 18th-20th National Assembly have been passed; Implementation of remote healthcare is made difficult by opposition from medical communities and civil organizations

Example of Regulatory Sandbox – Exception to Demonstration

- Testing allowed at a limited geographical region for 2,000 users for 2 years as an exception to demonstration for cardiac management service using MEMO watch (a watch-type electrocardiogram recorder)
- Utilizing the electrocardiogram data submitted by a patient, an HCP recommends the patient to see a doctor or refers him/her to the primary or secondary medical institutions



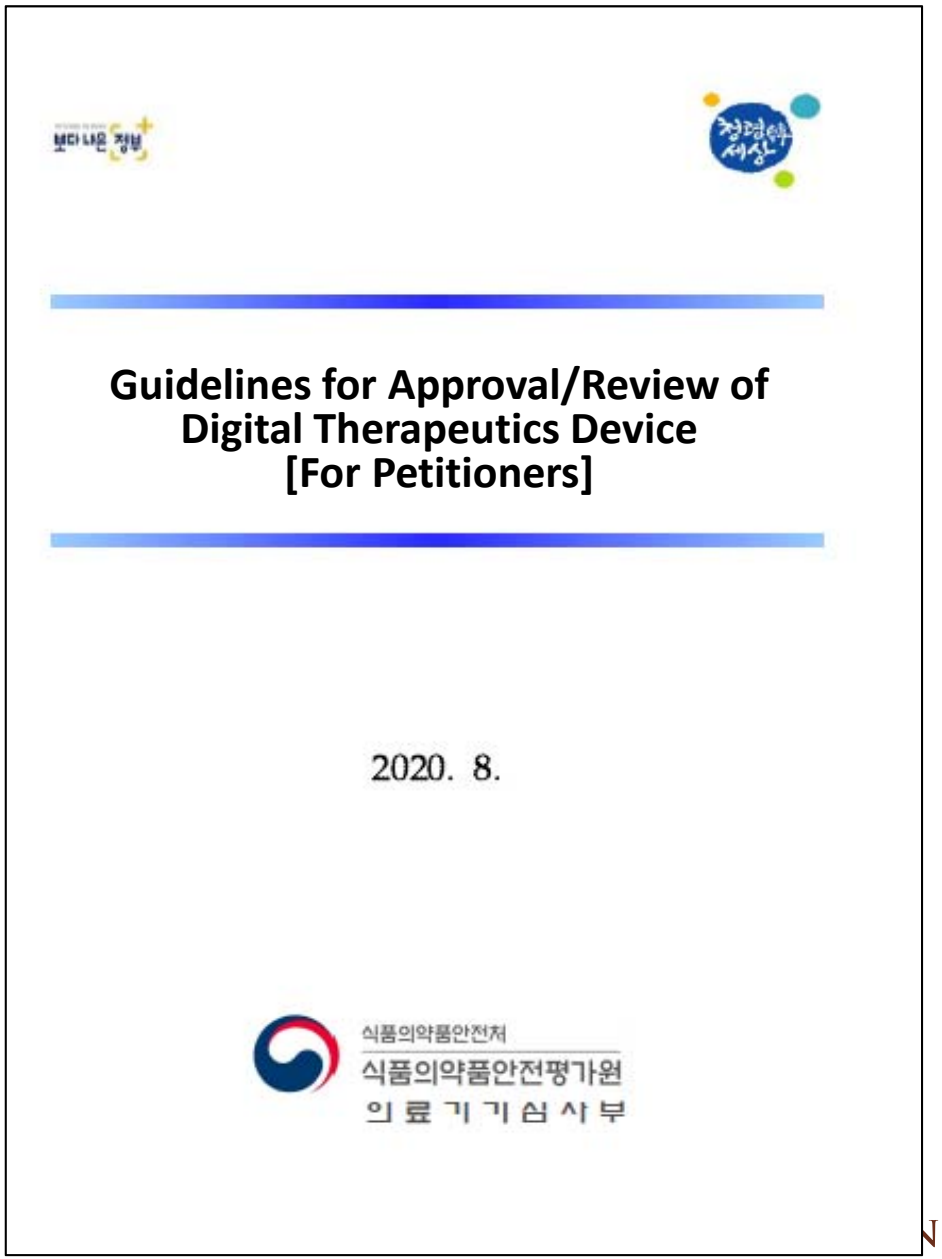
Under the regulatory sandbox, remote monitoring services are being provided to patients to a limited extent

2. Digital Therapy/Treatment

Digital Therapeutics Device

Examples of Digital Therapeutics

Company	Therapeutics	Details
Pear Therapeutics	reSET®	Cognitive behavioral therapy using a smartphone application for patients addicted to drugs; The first digital therapeutic to receive authorization from U.S. FDA in 2017
Akili	EndeavorRx®	Digital treatment for children suffering from ADHD using mobile games; FDA-cleared in June 2020
Proteus	Abilify MyCite	The existing tablet used for treatment of schizophrenia with a special sensor inside of it
Palo Alto	Freespira®	Digital application providing treatment of symptoms associated with post-traumatic stress disorder (PTSD)
Voluntis	Insulia®	Application calculating basal insulin doses for patients with Type 2 diabetes
Nunaps	Nunap Vision	VR software providing treatment of visual field defects after cranial nerve damage; The first SaMD to be cleared by the MFDS after clinical trials
LifeSemantics	Epil Breath	Application connected to health monitoring devices, providing rehabilitation treatment for patients with respiratory diseases



Digital Therapeutics Device

“Now” is the Time to Discuss Medical Care Fees for Digital Therapeutics Device

김홍진 기자 | 입력 2021.03.08 06:26 | 수정 2021.03.08 09:51 | 댓글 0

개발 지원 정책 속속 등장 "구체적 논의 필요한 시기"
"글로벌 시장, 디지

디지털치료기기 등 소프
었다는 의견이 제기되고

2020년 8월 디지털치료
련을 위한 본격적인 논의
야 한다는 것이다.

또한 식약처는 디지털치
설계방법 ▲임상적 유효
획을 발표한 바 있어 디
게 됐다.

Sun Min Kim, the Executive Director of the Health Insurance Review & Assessment Service (“HIRA”) also mentioned in her New Year’s address at the beginning of this year that she has “concerns over how to establish the insurance benefit for new forms of medical services, such as 3D and AI-based digital therapeutics, that are difficult to standardize based on the existing classification,” and pointed out the need to contemplate a new insurance benefit system for the next-generation of medical devices.

In February, HIRA’s executive director for development, Yong Myung Jang, announced at the Medical Journalists’ Association Council a plan to operate a working group in which Benefit Listing Department, Innovative Research Center, and Review & Assessment Research Department will participate to discuss the direction of how to have MFDS-cleared AI-based digital therapeutics be covered by health insurance.

Although this plan is welcomed by the industry, there are some voices calling for discussion on details of the plan, including the specific layout of the working group and composition of the subgroups that make up the working group.

Thank you

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Questions & Answers

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