Application of Special Cases for Health Insurance Benefits for Innovative Medical Devices

Suyeon Kim

The Graduate School
Yonsei University
Department of Medical Device Engineering and Management

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Suyeon Kim

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This certifies that the Doctoral Dissertation of Suyeon Kim is approved.

구 성 욱

Thesis Supervisor : Sung Uk Kuh

장 원 석

Thesis Committee Member #1 : Won Seuk Jang

권 병 주

Thesis Committee Member #2 : Byeong Ju Kwon

서 화 석

Thesis Committee Member #3 : Hwa Suk Suh

정 희 교

Thesis Committee Member #4 : Hee Kyo Jung

The Graduate School
Yonsei University

December 2024

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ABSTRACT IN ENGLISH

Application of Special Cases for Health Insurance Benefits for Innovative Medical Devices

This study introduces a special application plan for benefit compensation when identifying health insurance care benefits for innovative medical devices designated under the Medical Device Industry Promotion and Innovative Medical Device Support Act (Medical Device Industry Act), which took effect in 2020. During the Medical Device Industry Act, the provisions on preferential health insurance care benefits, which are crucial for marketing innovative medical devices, were deleted in the legislative process, losing the legal basis for preferential health insurance care benefits under the designation of innovative medical devices. The integrated examination system for innovative medical devices has been implemented through the revision of the notice of related laws since then, and institutional supplementary measures have been prepared, such as the temporary nonpayment of some innovative medical devices, by associating with the innovative medical technology assessment system. However, uncertainty remains about the benefits compensation for innovative medical devices after commercialization.

Separate compensation for medical care benefits entails a financial burden on health insurance, causing a burden on health insurance subscribers, under the domestic health insurance system. Therefore, the improvement measures that are introduced remain at the level of shortening the regulatory procedural period, temporary nonpayment, and screening benefits with a high proportion of patients' out-of-pocket costs, despite the long-standing demands of the medical device industry. The first medical device industry comprehensive plan(2023–2027), which was announced under the Medical Device Industry Act enforcement, also introduced the policy task of " innovative benefit introduction," but

related policy introduction has been delayed until now. Therefore, this study analyzed policies associated with medical device compensation, such as health insurance and new health technology assessment (nHTA), and analyzed the operational status and limitations of the innovative medical device designation system, which has entered its fifth year of introduction, to derive improvement measures to connect the innovative medical device designation system and special health insurance care benefits.

Hence, the institutional background of health insurance and nHTA after Korea's approval and the progress of related system improvement were analyzed. The limitations of the current system and improvement tasks were derived by analyzing the current state of the introduction of foreign systems related to innovative medical devices. The expiration date of the innovative medical device group subject to the designation of innovative medical devices considering the financial burden of health insurance benefits for introducing the special health insurance benefit compensation system in the medical device sector, and the operation plan of the revaluation system was presented to review the system that accommodates new technologies before being kicked out. Thus, a plan was proposed to expand the integrated review system for innovative medical devices in operation and relate it with the health insurance special system, and the scope was proposed to expand not only to the existing nHTA target but also to the technology innovation group and the public interest medical group among the innovative medical device groups that are included in the existing technology. Moreover, a system improvement plan was proposed considering the separate compensation mechanism for existing technologies and special cases for calculating therapeutic materials that cannot be separately calculated. Overall, revising the criteria for identifying and adjusting behavioral therapeutic materials related to the Medical Device Industry Act and the National Health Insurance Act was presented as a result of the study, and the improvement plan is expected to become an institutional basis for revitalizing clinical research throughout the industry by proving the technology of domestic medical devices as a clinical basis rather than simply receiving benefits.

Keywords: innovative medical devices, health insurance, reimbursement. nHTA

1. Introduction

1.1. Research Background

Determining new medical devices beyond the existing health insurance benefits under the domestic health insurance benefit determination system is extremely challenging. Medical devices are not identified through products, such as drug benefits, but are included in the fee for each medical practice. Medical devices utilized in the same medical practice are developed to reduce profits for medical institutions, which are the final beneficiaries, if the medical treatment benefits are not adjusted as a whole despite establishing a more improved-performance medical device. Medical institutions select relatively low-priced medical devices when they want to increase profits through the relevant medical practice under the current system, and receiving separate compensation is difficult despite developing a medical device with improved performance if it is classified as the same behavior when identifying health insurance care benefits.

The domestic health insurance benefit system is a structure in which patients who are recipients are only required to pay the same medical expenses regardless of whether they select expensive medical devices at medical institutions for the same medical practice. Thus, it is positive in terms of the cost burden, but it can limit recipients' options despite their desire to receive higher-quality medical care. Additionally, newly developed medical devices may be relatively expensive compared to existing medical devices in terms of the medical device industry, but R&D may shrink in the domestic benefit decision system, where selling them is difficult. Most of the sales of the domestic medical device market are formed through products that are guaranteed some profitability under the existing benefit system, and innovative medical devices, such as artificial intelligence (AI) and

rehabilitation robots, which have recently been actively researched and developed, are extremely low in actual medical institutions even after approval. Some therapeutic materials are individually compensated by calculating the benefits of therapeutic materials separately from medical treatment fees and have a benefit system that can be added to some parts of the existing benefits. However, they are included in medical treatment fees if they are not previously considered as separate therapeutic materials.

Conversely, drugs are individually compensated for drug benefits due to their nature, and drug prices are negotiated or nonbenefits are selected if the health insurance benefit determination level does not satisfy the benefits that the pharmaceutical company wants to receive. A separate negotiation procedure is not available in the case of medical devices that are included in the existing fee, and nonbenefits may be arbitrarily selected. A procedure involves applying for behavior adjustment; thus, the medical fee is calculated, including all medical products and labor costs utilized in the relevant medical practice, and the fee is rarely adjusted for one individual medical device. Accordingly, establishing a new medical device may be compensated for a separate price. Establishing an act through the nHTA system is decided, where the prerequisites differ from the existing medical practice in terms of legally set requirements. Applying a new medical device does not indicate that it is recognized as a subject of nHTA. However, a clear difference in the subject, purpose, and method of medical practice is classified as an nHTA subject. The nHTA subject must obtain permission from the Ministry of Food and Drug Safety (MFDS), undergo nHTA for approximately 250 days, and then decide on announcing the new health technology.[1] Following approximately 100 days of determination on health insurance medical care benefits, medical institutions can claim medical care benefits from patients after deciding on eligibility/non-reimbursement for medical care benefits. Concurrently, recognizing it as a new health technology does not indicate that higher benefits can be recognized than existing similar medical practices. The predictability of

price determination is low despite developing a medical device in this way and obtaining permission.[1] Therefore, companies face difficulties in developing new medical practices or devices that correspond to existing technologies to predict the possibility of entering the market.

The government has operated a permit system, a special case for nHTA, and a specific case for health insurance to support innovative medical devices entering the market since the permit, but it generally remains at the level of shortening the legal processing deadline for each civil complaint and operates a temporary nonpayment system. However, in the end, the policy on the methodology for separate compensation that the industry desires is missing. Newly developed medical devices do not necessarily have to receive separate compensation, but it would be a reasonable system that provides some compensation, and the industry may select accordingly. Until now, policies on separate compensation for health insurance care benefits have been introduced only for the technology when new technologies appear, such as AI and digital Therapeutics(DTx). However, no policy review and related research focused on institutional methodologies to cover the entire technology that will emerge.

1.2. Purpose And Methods

This study aimed to establish a plan to systematically introduce a separate compensation system when identifying health insurance care benefits for innovative medical devices. It is intended to present realistic criteria for adding medical care benefits for medical devices to which new technologies that will appear in the future are applied and to establish a plan to apply additional fees under the current fee-for-service system. Further, health insurance care benefits are operated with limited financial resources; thus, we will review separate special cases for medical care benefits and institutional measures for the mechanism of withdrawal.

The study analyzed the institutional background of health insurance and nHTA after Korea's approval and the progress of related system improvement. Further, we aimed to determine the limitations and improvement tasks of the current system by reviewing the current status of introducing foreign systems related to innovative medical devices. Furthermore, a revised bill of the Innovative Medical Device System Improvement Act is proposed by reviewing similar legislation, and an alternative is prepared by reviewing the opinions of stakeholders who oppose the introduction of the related special system.

2. General Status of the Designation System for Innovative Medical Devices

2.1. Overview of the Innovative Medical Device Designation System

Benefits/nonbenefits may be claimed from patients only after being registered as health insurance and approved by the MFDS, confirming whether they are eligible for health insurance benefits/nonbenefits (whether or not existing technology), to develop and market medical devices in Korea (Figure 1). Actual sales are possible after approval, but all medical devices utilized for medical practice at medical institutions, except for personal medical devices, can be charged to the patient with the identified benefit code or non-benefit medical treatment fee after deciding on payment. Medical devices used in medical practice cannot be individually charged to the patient and can be claimed according to the insurance premium for each activity determined by the Ministry of Health and Welfare (MOHW). Medical institutions avoid using them for medical treatment because charging patients for medical expenses before deciding on benefits/nonbenefits is impossible; thus, marketing them even after approval is challenging. Moreover, payment can only be determined through nHTA for new health technology without a health insurance care benefit code. The upper limit of medical treatment fees that determine the selling price of medical devices is identified in Korea, and claims are impossible in patients other than the upper limit.

Therefore, marketing new medical devices utilized in existing medical practices in separate price compensation is difficult, and medical devices used in new medical practices must undergo 250 days of nHTA even after licensing to identify the possibility of separate compensation. In Korea, introducing new medical devices to the market is extremely

challenging because of the limited options to receive additional payments in addition to existing benefits despite developing new medical devices. The health insurance benefit decision is not a system that identifies the cost for individual medical devices but a structure that determines the cost by covering medical practices, including medical devices. Compensating innovative medical devices in the current institutional environment is difficult; thus, the government enacted the "Medical Device Industry and Innovative Medical Device Support Act" in 2019 and introduced a system to apply special cases to innovative medical devices designated by the government to separate market entry.

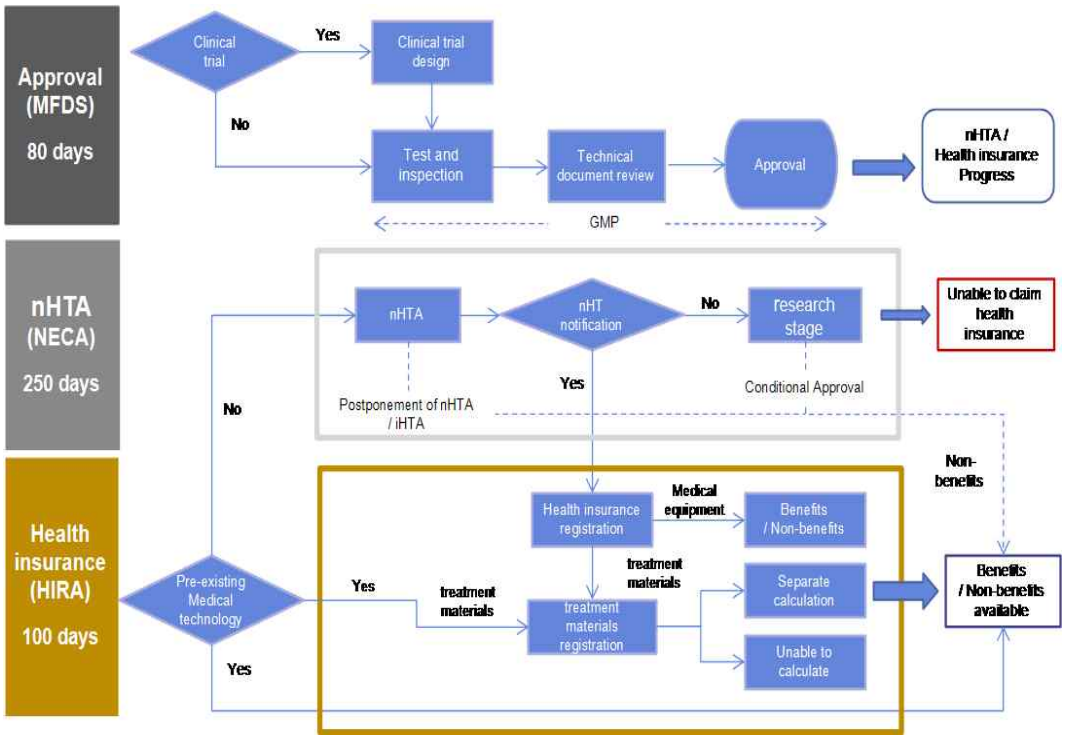

Figure 1. Procedures for entering the domestic medical device market[1]

An innovative medical device designation system was introduced following the enforcement of the Medical Device Industry Act in May 2020. The definition of an innovative medical device under Article 2 of the Medical Device Industry Act refers to a medical device designated by the MFDS under Article 21 of the Medical Device Act by applying advanced technologies in areas with high-technology intensity and rapid innovation, such as information and communication, biotechnology, and robot technologies, or by improving methods of use, which are expected to significantly improve safety and effectiveness compared to existing medical devices or treatments.[2]

The prerequisite for classifying innovative medical devices in the detailed designation procedure must correspond to the technology field included in the innovative medical device group notified by the Minister of Health and Welfare under Article 20 of the Act (Figure 2). The technology applied to innovative medical devices continues to develop; thus, revising the law following the development of the technology is limited when the law defines a specific technology. Accordingly, Article 2 of the Medical Device Industry Act defines the direction of the designation of innovative medical devices, and the Minister of Health and Welfare notified the detailed target as an innovative medical device group under Article 20 of the Act. Additionally, the technology can be deleted, re-designated, and added after re-evaluation every three years. Moreover, the effectiveness of the policy decreases if all medical devices are subject to the classification of innovative medical devices, so it has the characteristic of limiting the designation of innovative medical devices to select and focus on policy targets.

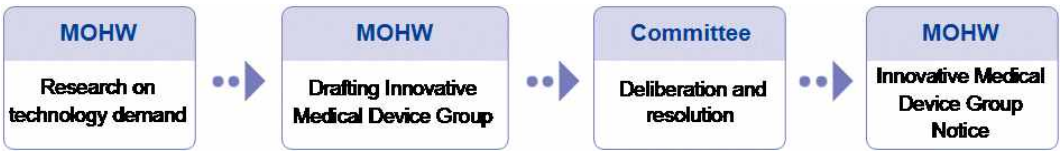

Figure 2. Procedures for classifying the innovative medical device group[3]

The current innovative medical device group classifies the definition of innovation following its policy purpose (Figure 3). It is classified as the medical innovation group and the existing technology, regardless of the high-technology group to support the rapid market competitiveness of new technologies, such as AI and robots, and the technology subject to medical device application, if the medical benefits are expected to be clear when using the medical device. However, the fields that secure medical benefits and short-term markets through performance improvement are categorized into four systems: the technological innovation group and the public service group, regardless of marketability, to define innovation.

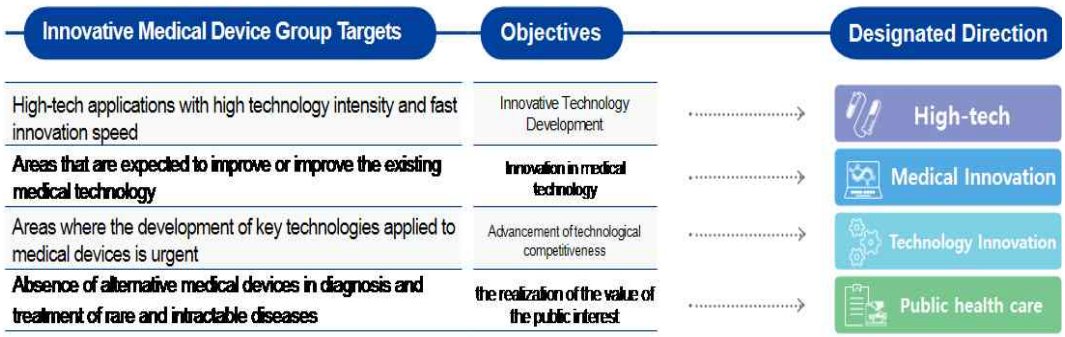

Figure 3. Classification and definition of the innovative medical device groups[3]

Accordingly, the state-of-the-art technology group announced 10 middle classification technologies through the innovative medical device group notification, and the remaining three technology groups indicate conditions for including the innovative medical device group because determining which technologies will appear is challenging (Table 1). The MFDS has the authority to designate innovative medical devices, whereas the MOHW is authorized to classify and designate innovative medical device groups, which is a prerequisite for classifying innovative medical devices under the current Medical Device Industry Act. This study aims to consider comprehensive support for medical devices from the MOHW's approval to the market entry to industrial development, including nHTA, health insurance registration, and government R&D support. Accordingly, the direct special case system was limited to the approval stage when the Medical Device Industry Act was first enacted. However, the integrated innovative medical device assessment system implemented in 2022 was introduced and became the basis for expanding the application to special cases for nHTA.

Table 1. List of innovative medical device groups[4]

Group	**Middle group**	
High-tech	1. AI/big data technology	6. Smart patient care technology
	2. Digital/wearable technology	7. convergence optical technology
	3. Medical robotics technology	8. Interventional procedures and surgical technology
	4. Convergence image diagnosis technology	9. Bio-fusion materials and device technology
	5. Convergence therapy technology	10. In vitro diagnostic technology
Group	**Requirement**	
Medical Innovation	• Absence of alternative medical technology • Possibility of improving medical outcomes • Possibility of improving patient benefits • The possibility of reduced social/economic costs	
Technology Innovation	• Urgentness for localization technology development • Potential for import substitution and entry into high-value-added markets	
Public health care	• Possible diagnosis and treatment of rare and intractable diseases • Possibility of responding to healthcare crises	

Medical devices that correspond to the innovative medical device group may be classified as innovative medical devices by the MOHW after consultation between the MOHW and the MFDS. Medical devices designated as innovative medical devices can be subjected to special cases in the licensing process and special cases subject to the certification of innovative medical device companies at the licensing stage, and some of the high-tech groups can be subjected to the innovative health technology assessment procedure although they are existing medical technologies (Table 2). This can be related to an nHTA procedure that enables existing medical technologies to receive health insurance benefits separately, and nonpayment can be applied during the evaluation period.

Table 2. Summary of the Designation and Support System for Innovative Medical Devices[2,3]

Category	**Designation of innovative medical device groups**	**Designation of innovative medical devices**
Designated authority	• Committee for the Promotion and Support of the Medical Device Industry	• Ministry of Food and Drug Safety
Designation Method	• Committee deliberation and resolution	• Ministry of Food and Drug Safety review and decision
Validity	• 3 years	-
Contents of the Support	• AI/Big Data, Digital/Wearable Technology Group Special case for integrated examination	• Special case for approval • Software Manufacturing Company Certification System • Support for the clinical trial design

2.2. Procedures for Designating Innovative Medical Devices

The procedure for designating innovative medical devices is categorized into general and integrated screening (Figure 4). The general review is a procedure that is subject to special cases in the licensing procedure after classifying innovative medical devices, and the agency under the MOHW reviews whether or not the innovative medical device group is eligible for categorization, delivers consultation opinions, and the MFDS finally designates it. The integrated assessment procedure for innovative medical devices is a procedure that can be applied to the nHTA system. The Korea Health Industry Development Institute, the Health Insurance Review and Assessment Service (HIRA), and the National Evidence-base Healthcare Collaborating Agency (NECA), which are affiliated organizations of the MOHW, assess the possibility of entering the market, whether they are eligible for medical care benefits, and whether they are eligible for innovative health technology assessment, when designating an innovative medical device. Additionally, the MFDS assesses innovation according to general review criteria. If necessary, the MOHW and the MFDS may form an expert consultative body to receive advice. Afterward, special cases for innovative health technology assessment are applied if the head of the MFDS designates it as an innovative medical device after an integrated examination of innovative medical devices, and it can be utilized at the medical site as a nonpayment during the innovative medical technology assessment period although it is an existing technology.

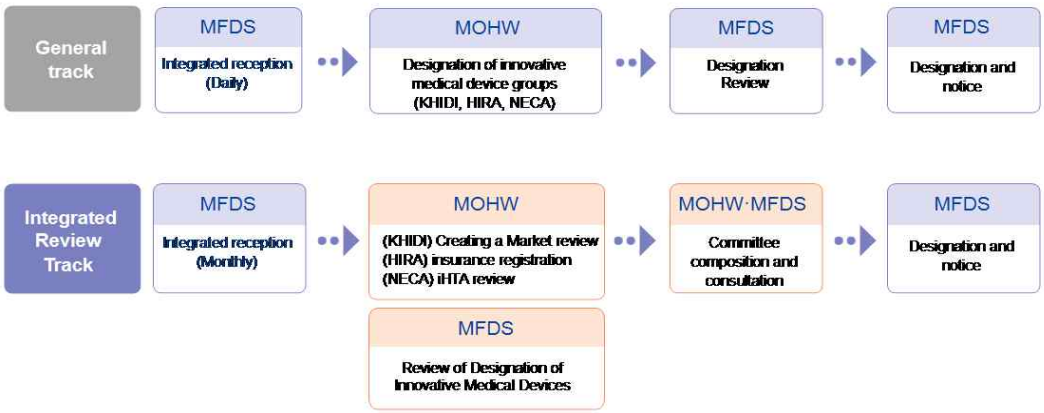

Figure 4. Procedures for Designating Innovative Medical Devices[2,3]

The innovative medical device designation system was operated with two tracks because the screening criteria for the general innovative medical device designation system are simpler than the integrated review system, and special cases can be applied at the pre-licensing stage. It can be quickly reviewed and applied to related special cases in areas with no health insurance benefit issues. Conversely, classifying an innovative medical device itself may be challenging if it meets the MFDS's sole evaluation criteria but does not meet the review criteria for the nHTA and health insurance stage in the case of integrated examination. It operates on two tracks, but the system is operated so that companies can selectively proceed with the procedure considering the characteristics of the medical device being developed. The innovative medical device designation system, which is a support policy, can rather act as a reinforcement of regulations in the case of a complete transition to the integrated review system. Currently, the integrated examination system for innovative medical devices is only possible in two of the high-tech groups, which are non-invasive, and have the direction of gradually expanding the system by reviewing the operation.[6]

The evaluation items of related organizations focus on the following factors when designing an innovative medical device. The MFDS assesses the initial development according to the general review criteria, the need to support innovation and fostering, and the innovation/differentiation/development of medical devices, whereas the MOHW evaluates the possibility of market creation, similarity, substitutionability, disease importance, clinical usefulness, and medical outcome improvement. The characteristics of the evaluation index are that the MOHW compares with existing approved medical device technology, whereas the MOHW focuses on comparing and reviewing the similarity of medical practice and the final medical effectiveness from a health insurance perspective. Moreover, innovation is reviewed by encompassing not only the technology itself but also the marketability.[5]

2.3. Status of Designation of Innovative Medical Devices

Currently, 74 innovative medical devices have been designated as of September 2024 after implementing the innovative medical device designation system in 2020, consisting of 56 general screening designations that receive preferential treatment for each approval stage by the MFDS and 18 integrated screening designations that are subject to special cases related to the innovative health technology assessment system (Table 3,5).[7] According to the major category of innovative medical devices, 69 cases were designated in the high-tech group, 2 cases in the technology innovation group, 2 cases in the medical innovation group, 1 case in the public service group, 37 cases in the AI and big data group, and 19 cases in the digital and wearable group, accounting for 75.6% of the total number of designations (Table 4). The designation of innovative medical devices related to diagnostic assistance SW and digital Therapeutics based on AI technology are subject to integrated examination, but the performance of the designation of innovative medical devices by other innovative medical device groups is low.

Table 3. Number of Designations of Innovative Medical Devices[7]

Year	2020	2021	2022	2023	2024	Total
Number of cases	5	9	13	29	18	74
(Integrated examination)			(3)	(9)	(6)	(18)

Table 4. Number of high-tech groups designated[7]

High-tech groups	Total
1. AI/big data technology	37
2. Digital/Wearable Technology	19
3. Medical Robotics Technology	3
4. Convergence image diagnosis technology	-
5. Convergence Therapy Technology	3
6. Smart Patient Care Technology	-
7. convergence optical technology	2
8. Interventional procedures and surgical technology	1
9. Bio-fusion materials and device technology	-
10. In vitro diagnostic technology	4

Table 5. Status of Integrated Examination Designation[7]

No.	Product names	High-tech groups
1	Medical Image Diagnostic Assistance Software	AI/big data technology
2	cognitive therapy software	Digital/Wearable Technology
3	cognitive therapy software	Digital/Wearable Technology
4	ECG analysis software	AI/big data technology
5	Medical Image Diagnostic Assistance Software	AI/big data technology
6	Medical Image Diagnostic Assistance Software	AI/big data technology
7	Medical Image Diagnostic Assistance Software	AI/big data technology
8	Cardiovascular Risk Assessment Software	AI/big data technology
9	ECG analysis software	AI/big data technology
10	Medical Image Diagnostic Assistance Software	AI/big data technology
11	ECG analysis software	AI/big data technology
12	Medical Image Diagnostic Assistance Software	AI/big data technology
13	Respiratory Rehabilitation Software	Digital/Wearable Technology
14	Medical Image Diagnostic Assistance Software	AI/big data technology
15	cognitive therapy software	Digital/Wearable Technology
16	Medical Image Diagnostic Assistance Software	AI/big data technology
17	Medical Image Diagnostic Assistance Software	AI/big data technology
18	Medical Image Diagnostic Assistance Software	AI/big data technology

Analyzing the designation status of innovative medical devices, there were high expectations for licensing, nHTA, and health insurance special cases when the system was introduced in 2020, but the legislative process excluded the nHTA and health insurance special cases. However, the designation of AI software medical devices that require special cases of licensing procedures has been concentrated, and AI and digital technology group designation continues to increase as it is related to the integrated review target. The nHTA or health insurance benefit special cases are more important than licensing special cases in the case of other technology groups. However, the innovative medical device designation system is ineffective because it cannot be applied to related special cases. Innovative technology development continues in various fields in addition to software-based medical devices, resulting in investment in commercialization, such as licensing by related companies, only if compensation is possible for health insurance benefits. However, companies in the domestic medical device field have difficulty generating profits even if new medical devices are developed.

3. Analysis of the Health Insurance Care Benefit-Related System

3.1. Health Insurance Care Benefit Determination Structure

Korea introduced a workplace medical insurance system for workplaces with 500 or more employees in 1977 since the enactment of the Medical Insurance Act in 1963, and medical insurance was expanded in the order of public officials and private school teachers, rural areas, and urban areas from 1977 to 1989.[8] In the early days, the examination of health insurance behavior differed due to the differentiation of medical insurance management institutions and the diversity of insurance systems.[9] However, the evaluation of health insurance behavior was unified with the enactment of the National Health Insurance Act and the creation of the HIRA in July 2000. Moreover, until 2000, no system evaluated whether newly developed medical technology had the same safety and effectiveness in clinical practice.[10]

The introduction of the national health insurance system in July 2000 required common standards, methods, and procedures for medical care benefits, including new registration methods for unregistered health insurance benefits.[11] Hence, rules on the standard of national health insurance medical care benefits and standards for identifying and adjusting undecided behaviors were enacted. Concurrently, undecided actions for which health insurance benefits were not determined were considered new medical technologies, and the judgment on whether new medical technologies that were not registered for health insurance could be registered was assessed through a specialized evaluation committee.[12] Such non-registered health insurance activities were evaluated through an application for identifying eligibility for medical care benefits. Among the benefits, medical activities were requested to apply for determining the eligibility for medical care benefits within 30 days

from the date of first performing the act that was ethically valid and medically recognized, and for drugs and therapeutic materials, within 30 days from the date of obtaining product approval or reporting the item. Simultaneously, systematic standards and methods for assessing the safety and effectiveness of undecided activities for which health insurance benefits were not determined remain unavailable. Difficulties arose when the applicant had to proactively prove this and unifying opinions among experts was impossible, such as cases in which final judgment was impossible, and cases in which the safety and effectiveness of medical technology were evaluated following the Health Insurance Act.[14]

Matters on medical technology evaluation were clearly defined in the law with the revision of the Medical Law in 2006. Rules on nHTA were enacted in April 2007, and a different medical technology evaluation system was introduced in earnest. Among the evaluations of existing undecided activities, the assessment area for safety and effectiveness is separated into 1) nHTA and 2) procedures for identifying eligibility for medical care benefits. Therapeutic materials were managed in connection with health insurance medical care benefits and non-benefit medical practices by dividing the procedure for determining the eligibility for medical care benefits into 1) behavioral and therapeutic materials and 2) drugs, and separating drugs within the scope of new medical technologies.[13]

The introduction of the nHTA system has resulted in a change that reflects the nHTA system in the process of determining receipt of medical care benefits. The application for determining receipt of medical care benefits for new medical technologies that have not been determined for health insurance benefits has been changed from “within 30 days from the date of the first performance of the act and therapeutic materials” to “within 30 days from the date of the first performance of the act with safety and effectiveness after being recognized as a result of the nHTA.” The application time was changed to “within 30 days from the first use of the therapeutic material by subscribers after recognizing the

safety and effectiveness as a result of the nHTA" in the case of therapeutic materials, from "within 30 days from the date of receiving the item permission or reporting the item" to "within 30 days from the date of receiving the item permission or reporting the item from the head of the Korea Food and Drug Administration," or "within 30 days from the date of first use of the therapeutic material by subscribers, etc., or for therapeutic materials subject to nHTA."[11]

Moreover, data on safety and effectiveness recognized by related academic societies or medical organizations, which were previously required to be submitted when applying for medical treatment benefits, were replaced by notifications of evaluation results such as safety and effectiveness of new medical technologies. The procedure was changed to submit additional notifications of evaluation results, such as the safety and effectiveness of new medical technologies to the existing procedures, in the case of therapeutic materials.[15] In 2009, the work on nHTA was transferred from the HIRA to the NECA. Since then, nHTA methods have been institutionalized through the enactment of regulations on the methods of nHTA in 2011.[16]

Following the revision of the rules on the standards for national health insurance care benefits in 2015, after the MFDS's approval, a procedure for determining the eligibility of a new health technology or an existing technology for medical care benefits was introduced before the assessment of new health technology.[17] In this procedure, the HIRA reviewed the clearness of the subject of the task along with the nHTA system introduction.

3.2. Health Insurance Medical Practice and New Health Technology Assessment

In Korea's health insurance management system, evaluations related to medical devices are categorized into nHTA and procedures for identifying eligibility for medical care benefits or nonbenefits. The Medical Act states matters concerning the operation of the nHTA system, and the National Health Insurance Act stipulates matters concerning the determination of eligibility for medical care or nonbenefits of medical treatment. However, the history of the system demonstrated that the nHTA began with an assessment method for new registration of unregistered health insurance benefits after introducing the single public insurance system across the country, and the two are closely related.[19]

All medical institutions, such as hospitals, established under the Medical Law in Korea are subject to the National Health Insurance Act, and expenses, excluding out-of-pocket expenses, are compensated by the state when medical services are provided to the public. The cost of compensation from the state after implementing medical care benefits in nursing institutions is categorized into actions, therapeutic materials, and drugs, of which compensation related to the use of medical devices is classified into actions or therapeutic materials.[11] In principle, implementing medical care benefits for behavioral and therapeutic materials provides benefits for all behavioral and therapeutic materials except those designated by the Minister of Health and Welfare, which is distinguished from drugs designated by the Minister of Health and Welfare to provide medical care benefits. Additionally, the use of medical devices related to behavioral and therapeutic materials is subject to strict management by the national health insurance system.

An act is a unit of health insurance benefits and nonbenefits for cases in which medical personnel uses a medical device, etc. to perform medical technology, such as diagnosis and treatment to a patient, and Korea has adopted a fee-for-service system for each act of receiving benefits classified by each act of medical care benefits.[11] The activities of medical care benefits and nonbenefits designated based on the list of benefits and nonbenefits of health insurance activities and the relative value score of benefits shall be calculated considering the workload of medical personnel, the number of resources invested, the risk of medical activities, etc., so that health insurance activities include the use of medical devices. Further, most of the health insurance activities reflect the characteristics of medical activities using medical devices.[20]

Therapeutic materials include consumable materials among medical devices required to provide medical care benefits, non-medical products under the Pharmaceutical Affairs Act, human tissues under the Act on the Safety and Management of Human Tissue, and other industrial products. Medical consumables that are too large to be included in the act or whose validity is recognized for separate compensation for each product may be compensated for other expenses for medical care benefit implementation, but other therapeutic materials are included in the act without separate compensation and their value is calculated. Separate compensation therapeutic materials are categorized by use and function, and middle classified and managed according to shape, material, specification, and usage method. Further, individual therapeutic material products, such as artificial hip joints, stents, and intervertebral fixation materials, are separately designated and managed. In particular, the list of therapeutic materials calculated by being included in nonreimbursable performance fees is not separately designated.[21]

The nHTA system assesses the safety and effectiveness of actions (including therapeutic materials) that are not included in the care benefit and non-benefit items under the National Health Insurance Act.[10,18] In general, cases that are not similar to the care benefit and non-benefit items under the National Health Insurance Act and the relevant research results are sufficient as assessment targets.[18]

The evaluation of new health technology is largely categorized into intervention procedures and in vitro diagnostic tests. It is a medical technology that does not have a separate list of medical benefits and nonbenefits in the case of intervention procedures, which may include 1) a universal procedure, 2) a new procedure, or 3) a procedure with a partially changed indication or treatment method. Questions may arise about the safety and effectiveness from the perspective of nHTA, if the relevant medical practice (medical technology) has a new indication (disease or symptom), procedure path, procedure, treatment method changes, or alterations in the energy source or therapeutic material of a medical device used for medical practice, and it may be considered subject to the evaluation of new medical technology.[22]

nHTA is conducted using a systematic literature review according to evidence-based medicine.[23] Evidence-based medicine is a field that has appeared in the field of medical research since 1990, and it is a study that investigates medical judgment objectively and transparently based on numerous clinical grounds, not just clinical experience.[24] A systematic literature review selects, collects, and analyzes various clinical grounds in evidence-based medicine according to medically agreed criteria, and consists of searching, selecting, evaluating, and synthesizing the clinical literature. In this case, methods, such as evaluation procedures for clinical literature and surveys for patients, may be used complementarily based on the evaluation technology.[25]

In principle, new medical technology evaluation is based on 1) the level of clinical evidence, 2) the amount of evidence, and 3) the research results that should be consistently positive.[22] Sufficient evidence that the safety and effectiveness are equal or higher than those of existing medical care benefits and non-benefit items is needed in the case of intervention procedures. The incidence of major complications should not be significantly higher than that of existing technologies in the case of safety by classifying and organizing major complications and concomitant diseases caused by the procedure. Additionally, the clinical effectiveness of the procedure should be properly demonstrated under certain conditions in the case of effectiveness.[26]

The results of the nHTA are largely classified into five categories. Results that are not subject to the nHTA were classified as an existing technology or assessed as an early technology, and those that are subject to the nHTA are evaluated as a medical technology with safety and effectiveness, a limited medical technology, or medical technology in the research stage.[18] Limited medical technology is a technology that can be utilized only in the requirements set by the Minister of Health and Welfare when it is identified as a limited medical technology based on the nHTA. During the introduction of the system, it was only possible to be recognized in the absence of alternative treatment or a treatment test for a rare disease. However, the scope was expanded to be recognized until it was judged that the potential clinical benefit was great.[27] Medical technologies that have been determined as early technologies or research-stage medical technologies based on the nHTA can be classified as limited medical technologies that meet certain requirements.[18, 27]

3.3. Special System for Approval-nHTA-Health Insurance Registration

3.3.1. Introduction of restrictive medical technology (2014.4)

The MOHW has introduced the “Restrictive Medical Technology Evaluation” system since April 2014, which enables exceptional medical institutions to treat diseases or rare diseases that do not have alternative treatment technologies, even before passing the nHTA. Claiming medical benefits from patients remains impossible despite the approval from the MFDS if they were subject to nHTA under the Medical Law, making their application in medical institutions difficult until completing the registration of medical benefits after the nHTA. Accumulating the clinical basis necessary for the evaluation of new medical technologies takes a long time even after the approval. Thus, the need to treat patients quickly is high in the case of diseases that do not have alternative treatment technologies or rare diseases. Further, regulations have been relaxed so that only some medical institutions can provide exceptional treatment even before they are finally recognized as new medical technologies.[28]

The nHTA indicated that the application target technology is a medical technology that safely treats diseases without alternative treatment technologies or rare diseases but has been eliminated due to a lack of evidence for effectiveness, and it is a technology notified by the MOHW. It is allowed to claim non-benefits only for the medical institution for up to 4 years if it is assessed as a limited medical technology. Medical institutions that have received limited medical technology evaluation must periodically submit patient treatment results and evidence for the effectiveness of the medical technology.

3.3.2. Expanding the exclusion of the nHTA(2014.5, 2016.5)

The MOHW obtained opinions from related industries that medical practices using newly developed medical devices are subject to nHTA, are highly burdensome for evaluation, and have low predictability of being subject to evaluation. It has established a standard to expand medical technologies that are excluded from the nHTA to the extent of the absence of concerns about public health and safety through discussions with the industry, the medical community, and related organizations, and deliberation by the nHTA Committee. In vitro diagnostic tests are similar to previous tests, or test methods that simultaneously conduct individual examinations are excluded from the nHTA. Moreover, medical technologies that are similar to existing medical practices, such as when some procedures have been added to the existing procedures or are simplified, have been excluded from the evaluation in the case of procedures performed by doctors. Through this, medical technologies classified as simple changes can be marketed by applying the same benefits and nonbenefits as existing medical technologies, including existing technologies. During the introduction of the system, approximately 55% (115 out of 209) of in vitro diagnostic tests were subject to nHTA and approximately 12% (13 out of 110) were excluded from the assessment. This paved the way for medical devices that do not require separate compensation for medical care benefits to be quickly put on the market without a separate procedure after licensing (Table 6).

Table 6. Types excluded from the nHTA[29]

Item	Type
In vitro diagnostic	• It is listed as an example of an inspection within the same classification
	• All of the individual inspection items included in the multiple inspections are proven to be safe and effective
Intervention	• The type of laser on the equipment used during surgery has been changed
	• If a treatment method has been added to an existing treatment
	• The medical practice performed directly by a medical professional is simply replaced using automated equipment

3.3.3. Permission-nHTA One-Stop Service (2014.8)

The MOHW and the MFDS implemented the “New Medical Technology One-Stop Service” in August 2014, which simultaneously performs medical device approval and nHTA. The total deliberation period for medical devices is shortened with the implementation of the system; thus, related industries are expected to release products to the market early and the public can access new medical technologies more quickly. Medical devices could be released to the market only after completing the approval of the MFDS and applying for a decision on medical care benefits (HIRA) during the implementation of the system. Therefore, the industry could not release products and people could not receive medical treatment through new medical technologies during the licensing period and the evaluation of new medical technologies.

To solve this problem, the MFDS, the Korea Institute of Health Care, and the HIRA introduced a system to share related data and proceed with the procedure in one stop. The legal processing period was 80 days for licensing, 360 days for nHTA, and 150 days for registration of health insurance care benefits, which took approximately 20 months, during the introduction of the system. However, the introduction of the one-stop service enabled procedural administration simultaneously, providing an institutional foundation to shorten the launch period of new medical devices and medical technologies from at least 3 months to 12 months.[30]

3.3.4. Postponement of nHTA (2015.6)

The MOHW has suspended the assessment of new medical technology for one year for medical practices using new medical devices approved by the MFDS after clinical trials to improve the system so that they can be utilized at clinical sites early. Previously, medical devices had to pass the nHTA after obtaining permission from the MFDS to be applied for medical insurance benefits and nonbenefits. Medical devices that have been approved by the MFDS after clinical trials have been suspended from the assessment of new medical technologies and can be utilized in clinical settings. A decision on medical benefits was applied through the nHTA after approval from the MFDS in the case of the current nHTA. The system has been improved if clinical trials are conducted at the approval stage so that it can apply for nHTA after one year of use in the field before the decision on medical benefits. Medical devices subject to assessment have been included in in vitro diagnostic medical devices, medical benefits have been applied as non-benefit, and the deferred period has been expanded to two years to continuously supplement the non-benefit advanced adoption system of medical devices subject to nHTA since the introduction of the system (Table 7).[31]

Table 7. Major improvements in the postponement of nHTA[31]

Category	Before	After
Target	Exclusion of in vitro diagnostic medical devices	In vitro diagnostic medical devices included
	When the purpose of usage is specified	When the purpose of the usage is specified
Requirements	"Comparative Clinical Literature" required	In vitro diagnostic medical devices are "Clinical performance test data" is accepted restriction on application
Restriction	No history of nHTA implementation	Allow only once even if you have a history of conducting nHTA evaluations
Period	1 year + up to 250 days	2 years + up to 250 days
Medical care benefits	Non-benefit	Non-benefit

3.3.5. Expanding the subject of exclusion from the evaluation of new medical technology in the inspection field and shortening the assessment period (2016.5)

The MOHW pushed for system improvement to expand the exclusion of nHTA in the field of inspection, such as in vitro diagnosis and genetic testing, and to drastically shorten the assessment period from 280 days to 140 days. This was because of the revision of the Medical Device Act, and in vitro diagnostic reagents, which were mainly used as general industrial products, were incorporated into medical devices in 2014 and classified as nHTA targets, and some changes in products that had been used in the medical field had to be subject to nHTA. The MOHW expanded the evaluation exclusion targets by clarifying the criteria, such as the purpose of the test, the exclusion of the subject for multiple tests, the exclusion of multiple tests in the principle, and the exclusion of genetic testing for

congenital rare diseases, to expand the scope of nHTA to the inspection field for improvement. Further, the inspection field is categorized by major factors, so the rapid evaluation system was introduced to drastically shorten the existing 280 days of nHTA to 140 days. Thus, medical devices in the inspection field, which do not have a separate benefit compensation issue, quickly enter the market. Concurrently, the direction of the special system for nHTA was to exclude evaluation and expedited examination in the diagnostic test field. Further, general medical practices were divided into two so that non-benefit advancements could be made through suspension of evaluation. However, the expansion of the release of medical devices subject to nHTA and separate compensation issues have emerged, including in vitro diagnostic medical devices, due to the recent development of technology in the inspection field.[32]

3.3.6. Introduction of an integrated examination system for medical device approval-nHTA (2016.5)

The MOHW revised the rules on nHTA, whose main content is to integrate and review medical device approval and nHTA. The period that took approximately a year was reduced to 80–280 days, as medical device approval and nHTA were sequentially conducted, thereby shortening the market entry period for medical devices by 3–9 months. Further, the medical device company applied for medical device approval (MFDS), nHTA (NECA), and eligibility for medical benefits and nonbenefits for medical benefits and nonbenefits (HIRA) through a single window of the MFDS, thereby alleviating the burden of individual applications and enhancing convenience.

Moreover, the scope of limited recognition of treatment under certain conditions was expanded, focusing on cases that were assessed as medical technology in the research stage due to a lack of valid evidence during the integrated operation of permission–evaluation. Additionally, the requirements were relaxed when applying the evaluation deferral system, so that clinical trial data that were submitted during approval by the MFDS in addition to comparative clinical literature may be attached, thereby partially resolving double regulatory issues in the nHTA-approval procedure. The requirements for the integrated examination can be applied only when the following requirements are met: if the manufacturing and import of medical devices and nHTA are simultaneously needed, if data on clinical trials are required for medical device approval, and if the purpose of using medical devices and medical technology is highly correlated.

The integrated operation of the permit assessment was conducted jointly by the MOHW and the MFDS in 2016 to promote system maintenance. The scope of the integrated operation in 2017 was expanded to “high correlation” in the second stage although the purpose of using medical device-medical technology was completely the same. A joint integrated review system for related organizations was introduced in 2018 to increase the efficiency of the integrated assessment among related organizations (Table 8).

Table 8. Comparison before and after the introduction of the system[33, 34]

Category	Before	After
Target	-	High correlation between the purpose of usage and medical practice
Procedure	Approval → nHTA sequential process	Approval + nHTA concurrent review
Application	Apply to MFDS, MOHW respectively	Centralized with MFDS
Review	MFDS, MOHW Individual review	MFDS, MOHW Share review and coordinate
Notification of the results	Individual notification	Unification notification
Deadline	360 days	80～140 days

3.3.7. Regulatory innovation and industrial promotion measures in the medical device sector (2018.7)

The government jointly announced the “Regulatory Innovation and Industry Promotion Plan in the Medical Device Sector.” Until now, the government has been making efforts to expand the R&D investment and shorten the regulatory period to foster the innovative and high-technology medical device industry as a new future industry in the era of the fourth industrial revolution. However, it has been emphasized that it has not been able to keep up with the rapid technological change in the medical device industry. In particular, the medical device field is where government regulations play a major role in public health and safety, and it goes through various regulatory processes from medical device development to the entry into the market (it takes up to 520 days).

To improve this, the government announced a plan to drastically innovate medical technologies (medical devices) with fewer safety concerns in the “advanced-post-evaluation” method. The main objectives were to convert the in vitro diagnostic field to post-evaluation and to enable future promising innovations and advanced medical technologies using AI, three-dimensional (3D) printing, and robots to enter the market first if minimum safety is secured, and then re-evaluate them based on abundant clinical evidence accumulated by utilizing them for 3–5 years in clinical sites. The government’s direction, with the announcement of this policy, was set to fostering the medical device sector and improving the system in the future, including the introduction of a separate track for innovative health technology assessment in the field of nHTA, reflecting technology development efforts when assessing therapeutic materials in the process of determining medical benefits, and enacting the Medical Device Industry Act.[35]

3.3.8. Innovative Health Technology Assessment (2019.3)

The MOHW revised and implemented the “Rules on New Health Technology Assessment” containing the contents of the “Separate Evaluation Track for Innovative Health Technology” and “Shortening the Evaluation Period for New Medical Technology.” Medical technology that converges advanced technologies and medical technologies with high social utilization value can now use separate assessment tracks rather than the existing nHTA. The nHTA, which evaluated the safety and effectiveness of medical technology according to published literature, broadly reviewed the basic safety and effectiveness before using new medical technology in the field. However, the use of innovative medical technologies that lack clinical grounds was delayed because of the evidence-based evaluation system. Hence, a “potential evaluation method” was introduced to supplement the existing literature-centered evaluation system.

Early market entry is allowed by introducing a method to evaluate the social value and potential of medical technology if medical technologies that were eliminated due to a lack of literature to assess their effectiveness in the existing evaluation system have high potential, such as dramatically improving the patient’s life or reducing the patient’s cost burden. Innovative medical technology that was introduced in the medical field through the “Innovative Medical Technology Separate Evaluation Track” must be reevaluated after 3–5 years according to the results utilized in the medical field. Temporary non-benefit and screening benefits are applied during the advanced market entry period. However, improvements were observed in detailed standards, such as delays in market entry due to latency in the decision on paying in the situation where temporary care benefits had to be decided before insufficient evidence, as well as restrictions on medical institutions similar to limited medical technology. Moreover, the policy target was a field to which innovative technology was applied, which was subject to nHTA and lacked evidence.

However, AI image diagnosis assistance SW and rehabilitation robots, which were judged to be applied during the introduction of the system, were judged to be subject to nHTA, and controversy over the effectiveness of the policy existed. Moreover, the nHTA period, which took up to 280 days, was partially shortened to 250 days by simplifying administrative procedures (Table 9).

Table 9. Comparison with the general nHTA system[36]

Category	nHTA	iHTA
Factor	Safety and effectiveness	Safety and effectiveness + potential value
Target	All	High-tech technologies such as 3D printing, AI, and robots. High social utilization value
Method	Systematic literature review	Systematic literature review + potential value

3.3.9. Simultaneous Review of nHTA and Healthcare Coverage Determination (2019.7)

The MOHW revised and implemented the “Rules on nHTA” and the “Rules on the Standards for National Health Insurance Care Benefits” that simultaneously perform the nHTA and Insurance Registration Review. This aims to shorten the market entry period by simultaneously proceeding with complex medical device regulatory procedures, including the integrated examination of permission-nHTA. The simultaneous progress of the nHTA and insurance registration review shortened the insurance registration review period (maximum 100 days) that occurred during the existing sequential process by conducting the nHTA within the nHTA period.[37]

3.3.10. Guidelines for Evaluation of Medical Care Benefits for Innovative Medical Technology (2019.12)

The MOHW announced in July 2018 the plan to prepare guidelines for applying health insurance to “AI-based medical technology (in the field of imaging medicine)” and “medical technology using 3D printing” through the “Medical Device Regulatory Innovation and Industrial Promotion Plan.” The main contents are new medical information that existing medical personnel cannot provide on the premise of using a device recognized as a medical device by the MFDS, or the additional value in health insurance is recognized to significantly improve the effectiveness of existing diagnosis and treatment if the appropriate research method proves what benefits are provided to patients. Additionally, the guidelines present the principle of compensation for benefits. The case of diagnostic assistance SW using AI technology, which was an issue at the time, was difficult to compensate separately because it was included in the video reading act as an existing technology.

This guideline classified nHTA targets when using AI technology as existing technology. Further, the criteria for improving the efficiency of doctors’ medical work, simple numerical measurements, and reading assistance purposes, such as area designation, etc., are classified as existing benefits, apart from improving diagnosis and treatment accuracy. The benefit compensation principle will be additionally recognized (compensated with separate fees such as item establishment and additional) if it is proven to benefit patients compared to existing actions or to reduce costs. This is based on a reasonable level of evidence such as external verification through cohort design accuracy research. Finally, the principle was proposed that the same medical device that was classified as an existing technology would secure clinical grounds, re-evaluate them, determine them as new medical technology targets based on evidence level, establish new benefits, or consider

separate compensation even for existing technologies. Hence, despite clinical trials at the licensing stage, the direction was indicated that the compensation level could be considered only when additional clinical studies were conducted to secure the evidence level and receive a judgment on the subject of new medical technology or to prove the level of separate compensation consideration as an existing technology (Table 10).

Table 10. Principles of compensation for benefits of innovative medical technology[38]

Category	Requirement	Target status
Level 1	• Technology that mainly reduces quick profits or indirect costs of medical institutions by increasing the efficiency of medical services	×
Level 2	• Technology with a level of diagnostic capability to similar to that of conventional behavior • Some of the existing actions have significant improvements, but overall they are similar to the existing actions	×
Level 3	• Significant improvement in the diagnostic performance over traditional medical practices • Create a new diagnostic value or treat effectiveness	○
Level 4	• In addition to Level 3, if cost-effectiveness is demonstrated	○

3.3.11. Foster the medical device industry and enforce the Innovative Medical Device Support Act (2020.5)

The MFDS designated innovative medical devices in consultation with the MOHW to implement an innovative medical device support system that includes step-by-step examination, priority examination, and special cases for innovative medical device software, with the implementation of the Medical Device Industry Promotion and Innovative Medical Device Support Act (Medical Device Industry Act) enacted in May 2019. The government designated innovative medical devices and included licensing, nHTA, and preferential treatment for health insurance benefits in the legislative process during the legislation of the Medical Device Industry Act. However, provisions related to nHTA and health insurance special cases were deleted and laws were enacted due to opposition from civic groups, thereby limiting the preparation of legal grounds for separate compensation, which is a requirement for the medical device industry. Moreover, the Medical Device Industry Act designates the operation of the designation of innovative medical device groups to determine technologies subject to the designation of innovative medical devices, which is designated by the MOHW, a ministry under the National Health Insurance Act. Hence, the MOHW and the MFDS work together to continuously supplement policies in applying special cases related to the designation of innovative medical devices. Further, the Medical Device Industry Act provides a policy basis for certifying and supporting innovative medical device companies. Some drug preferential treatment is applied to innovative pharmaceutical companies under the Pharmaceutical Industry Act. However, medical devices are included in the medical treatment fee unlike drug benefits that are individually set for medical care benefits.[3]

3.3.12. Introduction of an integrated examination system for innovative medical devices (2022.10)

The MOHW and the MFDS reviewed innovative medical devices, which correspond to AI, big data technology, and digital and wearable technology groups, and improved related regulations so that they can be used quickly in medical sites among the innovative medical devices designated under the Medical Device Industry Act in 2020. The main feature of the integrated examination system for innovative medical devices is that it is classified as subject to innovative health technology assessment if AI diagnosis assistance SW, which has been categorized as an existing technology despite designating it as an innovative medical device and disabling it to enter the market, is designated through an integrated examination.

Special cases for the designation of innovative medical devices were limited to special cases in the licensing process under the Medical Device Industry Act. However, related ministries used the system to provide a mechanism for compensation for innovative medical devices categorized in existing technologies (Table 11). The innovative medical device designation system is likely to be used in the introduction of an additional health insurance care benefit separate compensation special system, which can be a burden on financial needs, as it can operate a special case system for limited medical devices.

Table 11. Effectiveness of the Integrated Examination System for Innovative Medical Devices[39]

Category	Contents
Before	• Sequential and individual examinations by ministries and institutions, such as designating innovative medical devices (MFDS), confirmation of medical care benefits (HIRA), and innovative health technology assessment (NECA). → Most innovative medical devices are classified as existing medical technologies
After	• Designation of innovative medical devices by integrating and evaluating innovation, safety, effectiveness, etc. by relevant ministries and agencies → Improvement by expanding the scope of innovation recognition and simplifying innovative health technology assessment items
Effect	• Innovative medical devices are classified quickly for innovative health technology assessment → Medical site can be used as benefit after approval

3.3.13. Determination of medical care benefits for digital Therapeutics and AI innovative medical technology (2023.10)

The MOHW announced the application plan for innovative medical technology health insurance through the 25th Health Insurance Policy Review Committee in 2021. This is a special case for nHTA, relating to a temporary health insurance application plan required for advanced entry subjects to separate the evaluation of innovative medical technology introduced in 2019. 40 At the time of introducing the innovative health technology assessment system, the health insurance application was reviewed by screening benefits that differentially apply the patient's out-of-pocket rate; however, owing to the diversity of the technology field and health insurance characteristics, there is a limit to uniformly applying health insurance benefits out of consideration for patient options. The health insurance application principle applies 90% of the screening benefits when there is a high medical significance or there are no replaceable items in the existing health insurance area, in which case temporary nonbenefit registration is considered.[40]

Additionally, the inspection field can be determined as a nonbenefit considering the degree of influence on the decision on the treatment direction for diseases. First, two technologies designated as innovative medical technologies were temporarily subject to screening benefits and nonbenefits. (August 2022). The technology was designated in November 2020 and November 2019, and it took from one year and nine months to two years and nine months from the designation to applying temporary benefits.[41]

In July 2023, a temporary health insurance code was assigned to prepare a principle to be used. A suitable fee for each field was determined. Considering that artificial intelligence is a technology requiring the use of diagnostic assistance or a clinical field, it is classified as a similar category (Table 12) and compensated for each product at the 10% level of the case read by the image expert. Payments are made in the form of an add-on considering the time and frequency of the tests required in clinical practice for each field. Additional charges are applied if the potential value is highly evaluated while reviewing and evaluating innovative medical technologies. Additionally, in the case of applying as a benefit, an upper limit was applied for each field to prevent an excessive burden on patients.[42]

Table 12. AI Medical Technology Category[42]

Category
1. Pathological examination
2. Special imaging diagnosis (MRI, CT, PET, etc.)
3. Endoscopy, ultrasound
4. Except for 1 to 3, others (simple image diagnosis, functional inspection fee, etc.)

Considering the need to effectively manage digital therapeutics, mainly for mental and chronic diseases, a new fee for medical staff was established (Table 13). Considering the outpatient-centered explanation, education, and evaluation committee, the same fee was compensated regardless of the type of device and the choice of salary or payment. However, it was applied as a salary to encourage active monitoring when it was first introduced and to alleviate the burden on patients.

Table 13 Digital Therapeutics Benefits[43]

Category	Cost(KRW)	Contents
prescription fee	5,230	Training for use at first prescription
Effectiveness evaluation fee	16,130	Comprehensive rewards after use

3.3.14. Public hearings on ways to improve the market entry process for new medical devices (2024.9)

At a public hearing on ways to improve the "market entry procedure of new medical devices" on September 24, 2024, the MOHW and the Ministry of Food and Drug Safety stated, "We plan to improve the new medical device so that it can be used as a payment for up to three years if it goes through the Ministry of Food and Drug Safety's approval and the Health Insurance Review and Assessment Service's new technology."[44] Currently, except for some invasive medical devices in Korea, medical devices must go through the nHTA and health insurance registration process by the Korea Institute after licensing, reviewing new technologies entering the market. Up to 490 days are required after all of these procedures are completed. The government plans to proceed with the nHTA and health insurance registration process after the three-year nonpayment use period has elapsed. In the meantime, medical devices can be used as a benefit. When it is decided whether or not to register health insurance benefits, a system improvement plan to readjust medical expenses will be announced.

However, the government plans to strengthen clinical evaluation in the approval process by the Ministry of Food and Drug Safety to resolve safety concerns caused by shortening the market entry process. The system improvement plan is considering introducing it in the second half of 2025. If the system is introduced, products other than medical devices that have been temporarily determined as nonbenefits or selective benefits will be subject to the nHTA and the nHTA grace period. However, rather than targeting all medical devices, the Ministry of Food and Drug Safety will announce the targets of those medical devices and expand them step by step.

3.4. New Technology Health Insurance Separate Compensation System in Major Countries

3.4.1. USA

(1) NTAP, New Technology Add-on Payment

The Centers for Medicare & Medicaid Services (CMS) in the United States updates fees yearly on the basis of data collected by the Medicare Severity-Diagnosis Related Groups (MS-DRG) system for Medicare inpatients. However, NTAP (New Technology Add-on Payment) was introduced because it is difficult to calculate the basis for innovative treatment using new technology. This system compensates for the additional costs through incentives to encourage introducing innovative new technologies under the comprehensive fee system calculated according to existing technologies. NTAP application targets may be included in the comprehensive fee system if they pay temporary benefits for approximately 3 years after FDA approval or market launch, them in clinically, and prove sufficient value within the period. However, if this is not proven, the fee application will be canceled. Innovation, medical costs, and substantial clinical improvement criteria must be met to obtain approval from the NTAP.[45] Introduced since 2001, a total of 95 products applied for NTAP between 2003 and 2018; however, only 30% were approved.[46]

(2) New technology APC, Ambulatory Payment Classification

This system is introduced through the CMS' Outpatient Prospective Payment System to provide additional compensation for using new technologies, products, and services that cannot be applied to the comprehensive fee system when treating outpatients. However, innovation is the most essential criterion as APC targets new technologies with sufficient importance because the US Healthcare Common Procedure Coding System (HCPCS) grants unique payment codes.[45]

(3) TCET : Transitional Coverage for Emerging Technologies

The TCET pathway allows manufacturers to develop additional evidence after a medical device enters the market, supporting the scope of application of promising new technologies. The TCET program aims to accelerate new medical device development for patients with life-threatening, irreparably debilitating diseases or conditions that meet certain criteria. Nontraditional research design and data analysis methods, surrogate results, and real-world evidence can be used to support approving these devices. At the time of FDA approval, many devices using these strategies had significant evidence gaps concerning the reasonable and necessary legal standards required for Medicare coverage. For coverage decisions, CMS is older and has more complex medical needs. Additionally, clinical studies used to obtain FDA market approval require evidence for the benefits of the Medicare population that is inadequately represented.[47]

(4) Case of Artificial Intelligence/Digital Therapy Device Health Insurance Application

In the United States, 766 artificial intelligence-based products have been approved by the FDA and are 3.5 times more licensed than in Korea. Additionally, health insurance registration is optional because it can enter the market immediately after approval. Still, insurance codes such as the CPT or HCPCS codes are required for private and public insurance, which are often used in medical environments. In particular, in the United States, where private medical insurance is the basis, receiving the CPT code is crucial for spreading innovative medical services. The CPT code (Current Procedural Terminology code) is mainly used for medical procedures and services such as doctor's treatment, surgery, examination, and diagnosis and is evaluated and registered by the American Medical Association. It is not easy for innovative medical technologies using medical AI to receive the CPT code, as only 16 products were registered as of January 23. Most codes are temporarily registered as T codes (for about 3 years), while official codes are issued through reevaluation after temporary registration.[48]

The FDA has approved most medical AI but is not covered by US health insurance. The service must be paid for by the patient if there is no billing code. Radnet using breast cancer diagnosis assistance SW is an example. Radnet is a specialized center that provides image diagnosis services for outpatients through more than 400 centers in New York and California. For $40 paid by the patient, they provide breast cancer diagnosis assistance software that patients can choose from, not covered by health insurance. To operate these services, Radnet acquired Deep Health in March 2020 and is directly creating evidence.[49]

In the case of DTx, approximately 35 products have been approved by the FDA as of 2023, and these digital therapeutics are prescribed and used. In the case of 50 DTx, there are approximately 20 prescription products in Primera covered by private insurance. In this regard, a prescription CPT or HCPCS code can be used in the Medicare/Medicaid area or applied to individual private insurance programs. digital therapeutics are also widely used as medical devices that can be used without a doctor's prescription as OTC.[51]

3.4.2. Japan

The Japanese health insurance system uses a fee-for-service process, and a new functional and new technology medical material (C1) and (C2) system are in operation to pay medical expenses for new medical technologies. The technology used in the medical device has already been evaluated for new functional medical material (C1), but a new functional classification is required. Additionally, it is calculated by assessing whether or not the five additional criteria have been met. New functional and new technology medical materials (C2) require a new functional classification; because the technology using the product has yet to be evaluated, so a new technical fee must be established and an insurance coverage evaluation must be made The compensation standard uses the cost calculation method considering the manufacturing (import) cost, sales cost, general management cost, operating profit, distribution cost, and consumption tax.[52]

In April 2022, Japan's Ministry of Health, Labor and Welfare added requirements for managing image diagnosis assistance software using AI technology in "Image Diagnosis Management Addition 3," an item for CT and MRI scans. Through the "Image Diagnosis Addition 3," additional fees are recognized when proper safety management of AI image diagnosis software is performed according to safety standards in hospitals that meet specific facility requirements. Examples of AI medical technology to which Japan's health insurance benefit addition number is applied include nodosa and CXR-AID. First, Iris' nodosa is a medical device that analyzes images and questionnaire information of the pharynx with an artificial intelligence-equipped pharyngeal endoscopy system to detect and assist in diagnosing influenza virus infection characteristics. This is the first time in Japan that an AI medical device has been applied to functional and new technology medical material (C2) insurance. It was applied in 2022.[53]

CXR-AID is a medical device developed based on the Lunit Insight CXR, a domestic medical artificial intelligence company sold by Fujifilm and officially certified in January 2023 for three additional items for image diagnosis management by Japanese health insurance. CXR-AID is an AI image analysis solution that assists medical staff in diagnosis by detecting abnormal findings in chest X-rays. CXR-AID is paid a total of 340 points (equivalent to 3,400 yen) by adding 40 points according to the use of the AI solution to 300 points for the existing number of photographers. Additionally, Bruno and Neurofit's AI software has been certified. However, in the case of AI SW, because it is a medical material in the general comprehensive group A rather than the new Japanese medical material technology C, additional charges are applied to image diagnosis software that utilizes artificial intelligence-related technology. Similar to Korea, the extra fee system for AI software has been introduced in Japan, but only in a very limited area.[53]

Additionally, smoking is a social issue in Japan. Regulations are being strengthened to solve this problem, such as banning smoking in public places during the Tokyo Olympics. Japan's CureApp company developed digital therapeutics to stop smoking to solve these social problems. Its effectiveness was proven through a large-scale clinical trial of 584 people, after which it was registered in health insurance with the Ministry of Health, Labor and Welfare's approval. Claims in the amount of 254,000 yen for a six-month period can be made.[54]

Health insurance products from CureApp are for managing high blood pressure. These products have also been proven to be effective through well-designed clinical trial models and a clinical trial involving 390 patients. It can be used for 8,300 yen monthly. Compared to the complex prescription process and limited scope of these products in the United States, Japan has the advantage of prescribing digital therapeutics through a simple process, providing access for the whole nation with a national insurance system. Unlike other countries, Japan's unique processing procedure, which carries out medical device licensing and health insurance registration by the same ministry, allows the Ministry of Health, Labor and Welfare to make decisions immediately at the Ministry of Health, Labor and Welfare (PMDA) and Health Insurance Registration (Central Social Insurance Council (Chuikyo)), which is registered as health insurance four months following approval.[54]

3.4.3. Germany

In Germany's health care system, paying inpatient medical expenses for new medical technologies is operated in two ways: the New Medical Technology Additional Payment System and the New Methods for Treatment and Screening (NUB). In the New Medical Technology Additional Payment System, individual hospitals receive additional medical expenses by individually negotiating innovative diagnoses and procedures with the Health Insurance Association, the operator of public disease insurance. It is designed for additional medical expenses to be covered on the basis of the cost data submitted by individual hospitals.

The innovation fund system, introduced in 2005, pays additional medical expenses for new and innovative diagnosis and treatment methods not coded into the German-Diagnosis Related Group (G-DRG). It is a compensation system for innovative services and technologies used in addition to procedures included in DRG semen, to compensate for the period from introducing new medical technology to paying G-DRG-based medical expenses. It can be updated every year up to G-DRG integration through a one-year contract. Germany enacted the Digital e-Versorgung-Gesetz in 2019 and introduced a Digital Health Application (DiGA) that doctors or psychotherapists can prescribe. Germany's Food and Drug Administration, the Bundesinstitut für Arzneimitel and Medizinproduckte (BfArM), is involved in applications and procedures for listing in the DiGA directory, allowing DiGA to be prescribed through the fast-track option to more than 730,000 people insured under the German Statutory Health Insurance Scheme. DiGA, which can enter the fast track, is a class I medical device or class IIa medical device (invasive device) for treating diseases, whose primary function is based on digital technology.[55]

The evaluation period of BfArM in the fast-track procedure is up to 3 months upon receiving the complete application. This procedure examines the manufacturer's information on the product characteristics required, from data protection to user-friendliness and reviews the manufacturer's evidence on the positive management effects that can be achieved with DiGA (Figure 5).[56]

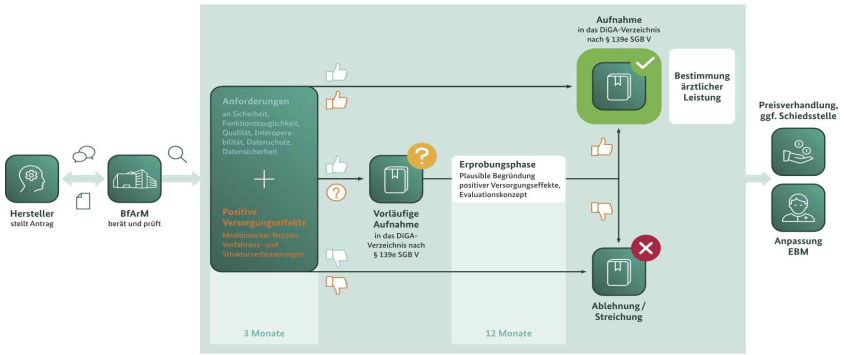

Figure 5. DiGA Fast-Track Registration Procedure for BfArM [56]

As of September 2023, a total of 55 cases were registered in Germany, 21 cases were not registered, 110 cases for self-receiving, 9 cases for cancelation of registration, and 13 cases for registration review. Nine cases canceled after registration were not secured for clinical effectiveness, six were self-receiving, and three were self-receiving. (Figure 6)

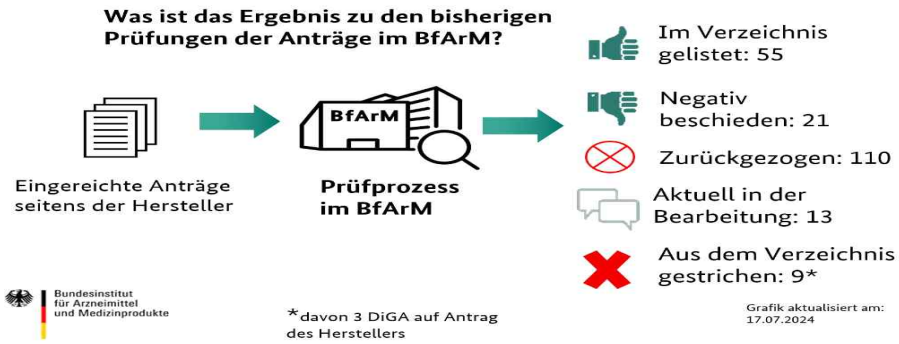

Figure 6. DiGA registration status[57]

3.5. Comparison of the Health Insurance Care Benefit Determination System at Home and abroad

3.5.1. General analysis of designating domestic and foreign innovative medical devices and the health insurance registration system

Korea and the United States have created systems for innovative medical devices and support rapid licensing. However, these innovative medical devices are not directly connected to health insurance instead, they are linked to health insurance only for some related products through a separate evaluation. The insurance linkage system has recently begun to be introduced, and Korea has established an integrated screening system for innovative medical devices, which has been evaluated by related ministries, and linked to innovative medical technology. As of 2024, a total of 18 products were designated.

In the past, the United States established an MCIT system that temporarily linked all innovative medical devices to health insurance. The TCET system was newly launched on 24.8.12 based on the opinion that it is inappropriate to provide medical technology that has not yet been proven effective to Medicare patients. The main purpose of TCET is to provide temporary health insurance support for innovative medical devices that fall into the Medicare (over 65 years old) benefit category through separate evaluation. Approximately 5 devices are selected annually. Germany has established the DiGA system that supports health insurance for digital health apps. A total of 65 have been designated, with 36 official registrations, 21 temporary registrations, and 9 products deleted after evaluation. This system is used at the price suggested by the company for the first year, after which the price is renegotiated. Japan has established a system called Image Diagnostic Management Gassan 3, which adds 40 points to the existing medical practice for products selected through evaluation by the Japanese Academy of Radiological Radiation. Currently, 30 products are designated. The 40 points correspond to 400 yen.[53]

Korea and the United States have different health insurance systems; however, there is an institutional mechanism that applies to special cases by designating innovative medical devices at the licensing stage. If this is supplemented with a policy decision, converting to a system that applies special health insurance compensation to innovative medical devices will be possible. Germany's special exemption system, which is limited to digital health-related products, and Japan's warrant diagnosis additional fee system were similarly compensated for innovative health technology assessment targets among nHTA targets by referring to certain aspects of Korea's health insurance. Although Korea's innovative medical device designation is an institutional device for applying special cases to all medical device technologies, it conservatively approaches separate compensation.

3.5.2. A comparative analysis of domestic and foreign medical technology evaluation systems

The United States, Germany, Japan, the United Kingdom, and Korea go through the process of registering medical devices, after undergoing medical technology evaluation, for health insurance. In Korea, however, technologies not registered in health insurance can be classified subject to nHTA and can only be registered in health insurance through nHTA. Essentially, it cannot be claimed by patients before being registered in health insurance. However, in the United States, Germany, Japan and the UK, even before being registered as health insurance, new medical practices can be performed at the patient's own expense or at the expense of private insurance as recommended by medical staff and with patients' consent. If evidence is accumulated this way, the new device can apply for medical technology evaluation and, if approved, be registered under health insurance.[53]

3.5.3. Analysis of the Health Insurance Care Benefit Improvement System in the nHTA Stage in Korea

Unlike in foreign countries, most medical devices in Korea can be used at medical facilities if they are licensed. Technologies not listed in the health insurance system are classified as subject to nHTA, through which they can enter health insurance through. Since it is very difficult to pass the nHTA after approval of a medical device, accumulating clinical evidence by utilizing evaluation deferral or an innovative health technology assessment that supports the creation of clinical evidence temporarily is a method for entering the medical field through nHTA. Although it cannot be used immediately, unlike in the case of the US or Germany, this method can be used temporarily through a separate review and evaluation procedure. However, if a new device is designated as subject to nHTA and then rejected after undergoing nHTA, it is considered a significant challenge in the industry. Essentially, it means that using of the medical device in the market and in the medical field is restricted.

In response to the industry demands, related ministries have continuously improved related systems; however, as domestic health insurance coverage has strengthened, the entire benefit policy was limited except for benefits such as overseas cases. Therefore, the improved system has been prioritized to shorten the legal treatment period by simplifying similar or duplicate administrative procedures and has applied a limited temporary benefit/selective benefit policy. Although this policy is to access a temporary benefit, various systems have been introduced depending on the specific target, increasing the system's complexity.

Separate compensation issues, which are the practical demands of the industry that develops innovative medical devices, are also temporarily applied to limited medical devices. No separate medical devices are subject to compensation that have reached the stage of full coverage. There is no change in that all innovative medical devices that want to be compensated must undergo an nHTA because the current health insurance system is a benefit decision policy based on an nHTA establishing a separate medical practice code. No policy decision has been made for innovative medical devices thus far, despite some separately calculated therapeutic materials or benefits that can be determined according to the National Health Insurance Act.

When analyzing the major systems among the advanced policies before the improved nHTA, considering the limited medical technology as an advanced technology is difficult because only separate publicly announced technologies can be used, and nHTA must be performed at least once. Advanced admission systems that can be used immediately after approval include evaluation deferment of new medical technology or innovative health technology assessment. Each has a unique timing of introduction, application targets, and application requirements; however, the difference in the implementation form is gradually decreasing through ongoing system improvements. However, research must be conducted when using innovative medical technology for invasive purposes, and there is a difference that requires IRB deliberation to conduct research. Another difference is that in the case of innovative medical technology in relation to whether or not health insurance is applied, a separate code is generated as an innovative medical technology, and evaluation deferral can be used without a separate code.[44]

To utilize advanced technology, it must first be classified as the subject of nHTA first. A total of 145 medical AI software licenses were issued in 2022, but most of the image diagnosis assistance software using medical AI were classified as existing technologies. Only two products could enter the medical field with new medical technology deferred before the system was improved ('22.October). If it is classified as an existing technology in Korea's medical environment, it cannot receive additional value compensation even despite being new technology. Therefore, there is a limit to creating clinical grounds because the factors of introduction in hospitals are not large. Additionally, even if it is designated as an innovative medical device subject to nHTA, such as digital therapeutics, it takes a long time to go through the nHTA licensing, which is a problem. In October 2022, the MOHW, affiliated organizations of the MOHW, KHIDI, NECA, HIRA, and the MFDS provided an opportunity to compensate for the value of innovative medical technology to solve the difficulties of innovative medical devices entering the market. Related ministries and institutions discussed the possibility of rapid field use.

If the integrated examination of innovative medical devices was classified as an existing technology in the past, it is not connected to the innovative medical technology system; however, if it passes the integrated examination, it can be linked to innovative medical technology. It does not target all products, but the target was selected based on technologies that are expected to have advanced issues. Only those products that satisfy conditions 1 and 2 at the same time can be applied for. Although it is currently being implemented only for a limited group of innovative medical devices, it is significant that an institutional foundation has been established that can link the expanded scope of the target and the separate policy of special compensation for compensation. The integrated examination has reviewed the parts that the Ministry of Food and Drug Safety, the Korea Institute of Health, and the Korea Appraisal Board have each evaluated in the approval process, providing an opportunity to accumulate clinical evidence through actual use in the

medical field by linking them with innovative medical technology after designation. Thus, depending on the company's choice, it is possible to claim selective benefits or benefits. As of August 24, a total of 18 products were designated as innovative medical devices through an integrated examination, and 16 technologies have been announced so far. Of these, 14 technologies use medical AI and 4 are digital therapeutics, which are not applicable except for noninvasive medical devices related to digital health.[7]

3.5.4. Analysis of separate compensation cases for medical device health insurance

(1) Current price of artificial intelligence/digital therapeutics devices (new medical technology)

As shown in Table 14, medical AI and digital therapeutics devices have been able to apply for selected benefits since December 2023 per the revised Health Insurance Behavior and Nonbenefit List and Salary Relative Value Score (notification). Therefore, if the screening benefits are applied, the additional fee of the imaging specialist will be compensated at approximately 10% of the applicable activity fee. In contrast, if the benefit is selected, it can be calculated up to 10%–30% of the maximum total activity fee.

The Health Insurance Review and Assessment Service separately discloses information about digital medical technology benefits. When the system was introduced, 3 out of 19 innovative health technology assessment technologies were listed as benefits, and 69 medical institutions used the technology. an AI activity-related company, Company L's sales are estimated to be approximately KRW 60 billion in 24 years, up from KRW 25.1 billion in 23 years, compared to sales before and after applying domestic benefits following the first medical device license issued in 2019.[58]

Table 14. Current status and criteria for registration of nonpayment of medical care benefits for digital medical technology(2024)[59]

Medical Technology Name	nonbenefit (KRW)	Number of medical institutions
AI-based 12-guided electrocardiogram screening	4,000	12
AI Analysis and Utilization of Fee-Radiation Special Images	18,100	48
Cognitive Behavioral Therapy in Patients with Chronic Insomnia	25,390	9

(2) The therapeutic material

Medical devices designated as technology innovation groups corresponding to existing technologies have also been listed for selective benefits by determining (separate calculation) therapeutic materials after the 2018 certification. The medical device was certified as a second-class product in the licensing stage and without submitting clinical trial data. If it was impossible to Calculating the price of the product separately at the health insurance registration stage made it difficult to properly determine the price of the product; thus, it was impossible to sell. However, after applying for the decision of the therapeutic material through consulting with the joint Medical Device Industry Support Center, the compensation was set at a higher price than the separate calculation and cost of existing similar therapeutic materials (Table 15).

The start-up company, which mainly develops two separately calculated therapeutic materials products, achieved sales of KRW 700 million in the first year following its 2019 certification, increasing to KRW 17.2 billion in 2023.58 This shows that the separate compensation has a great impact on developing company sales regardless of whether it is paid or not. Furthermore, the policy effect is limited in the case of expensive therapeutic materials if the out-of-pocket rate is high.[60]

Table 15. Case of separate cost calculation of existing medical technology therapeutic materials[60]

Pay standards	Name of the therapeutic material	Patient burden ratio	Decided year
screening benefits	multilateral induction bipolar cutting machine	80%	2019
	multilateral induction surgical instrument	50%	2019

(3) Full PACS

A separate compensation case often mentioned when introducing a separate number of medical AI devices is the Full PACS case, which was first introduced with a salary in 1999. At the time of introduction, it was introduced at approximately 3,000 won per medical image, when a medical system replacing film images increased; however, the salary was gradually reduced (approximately 20% reduction for 3 years) in 2009. Despite the issues due to cuts, introducing prepayments by predicting the effect of improving the existing medical system through reading analog film images established a policy case. Therefore, the penetration rate of PACS and EMR in Korea at that time was approximately 92%, the number first in the world. Accumulating high-quality standardized medical image data was the basis for domestic companies preempting developing the image diagnosis assist SW field among AI medical devices.[61]

(4) Dental implants

Dental implants, included in the 2014 nonbenefit act, have been gradually converted to benefits. Using existing dentures as a paid technology, which was converted after being a nonbenefit, may be a representative case in the field of medical devices. The bill for dental implants and related therapeutic materials in 2023 was approximately 66.7 billion won. The right to cover patients has been expanded by converting a medical technology as a benefit into benefits after long-term use in consideration of health insurance finances. There are many cases in the dental field in which the same treatment was also determined to be a benefit depending on the material. Despite being a benefit, it is possible to enter the market as a benefit treatment selected by patients, such as in the field of beauty medical devices. According to the estimate of benefit medical expenses in 2023, dental hospitals account for approximately 400 billion won of the total benefit medical expenses of approximately 5 trillion won, accounting for 8.1. Despite being paid, dental implants are limited in quantity, making them the fourth-largest item in medical expenses (approximately 14.9 billion won) among all benefit medical practices.[61, 62]

4. Application of Special Cases for Health Insurance for Innovative Medical Devices

4.1. Direction of the application target selection

The system for determining nHTA and health insurance benefits related to entry into the existing medical device market is summarized as follows. 1) If it is not subject to nHTA, it is impossible to compensate separately for improved medical practices; 2) It is difficult to predict the possibility of compensation until the main benefit decision has been made, even if it is subject to nHTA; 3) Detailed institutional differences such as deferral of evaluation and innovative health technology assessment exist, but among medical devices that have undergone clinical trials during the approval process, temporary payment and screening benefits can be applied for a certain period of time.

In Korea's care benefit decision system, which calculates the cost of benefits for each activity under the National Health Insurance Act, medical devices are just one component determining the relevant activity fee. As of 2023, 7,065 domestic medical device licenses, certifications, and reports were made. 63 Considering the entire medical device as a subject of review of health insurance special cases should improve the overall health insurance care benefits system. Most licensed, certified, and reported medical devices are manufactured by individual companies with similar medical devices that have already formed a market; thus, targeting all medical devices is inefficient for system operations. Additionally, since introducing a separate compensation special system for health insurance entails a financial burden on health insurance, applying it only to the target should be considered.

Therefore, the special health insurance targets innovative medical devices designated per Article 21 of the Medical Device Industry Act. The system design is limited to medical devices that have gone through the integrated examination track of the Ministry of Food and Drug Safety and the MOHW (KHIDI, NECA, and HIRA) in the designation stage. This is because it is a model that submits cases for additional medical benefits among innovative medical devices subject to the special case system for conditional advanced imports (temporary benefit/selective benefits) before the nHTA is in operation; if the basic target varies by policy, it can cause confusion in the system.

Currently, the integrated screening targets are limited to the AI, big data technology, and digital and wearable technology groups, which are lower-level technologies in the innovative medical device groups announced by the MOHW per the Medical Device Industry Act. This system improvement plan aims to expand and propose the target to all innovative medical devices outside the relevant technology group. Therefore, the legal system improvement plan was reviewed together to expand the scope of the current integrated examination system for innovative medical devices and to apply special cases to health insurance benefits. The procedural regulation of entering the domestic medical device market differs from the competent ministries to the screening institution at each licensing, nHTA, and insurance stage. Each licensing procedure is handled by the Ministry of Food and Drug Safety in compliance with the Medical Device Act (including the In vitro Diagnosis and Digital Medical Products Act), and the Korea Institute of Health Insurance Review and Assessment is responsible for the nHTA under the MOHW's jurisdiction. Each law and operating institution is different and defines "innovation" differently, confusing the medical device industry.

The innovative medical device designation system under the Medical Device Industry Act and the nHTA system, a separate nHTA track according to the Medical Act, innovative health technology assessment and care benefit determination system must be decided before introducing a new system. The policy definition of “innovation” for developing the innovative medical device health insurance special system was conceptualized (Figure 7). All medical devices developed in the industry are licensed, certified, and reported with minimal safety and effectiveness requirements after review and approval by the Ministry of Food and Drug Safety. Technologies in technology groups, according to the definition of innovative medical device groups under the Medical Device Industry Act, are subject to review for innovative medical devices. Therefore, innovative medical devices designated through integrated examination are subject to innovative health technology assessment under the Medical Act and are subject to value compensation.

However, this is limited to the subject of nHTA among innovative medical devices. nHTA is defined as a case where the subject, purpose, and application method are different from existing medical technologies, regardless of technological innovation, and the changed medical technology does not necessarily mean the medical technology meets the definition of innovative. Even if it is not subject to nHTA under the Medical Law, it includes areas that must improve existing medical devices and medical effectiveness. Additionally, they must be developed in the public interest in areas where domestic supply and demand are difficult.

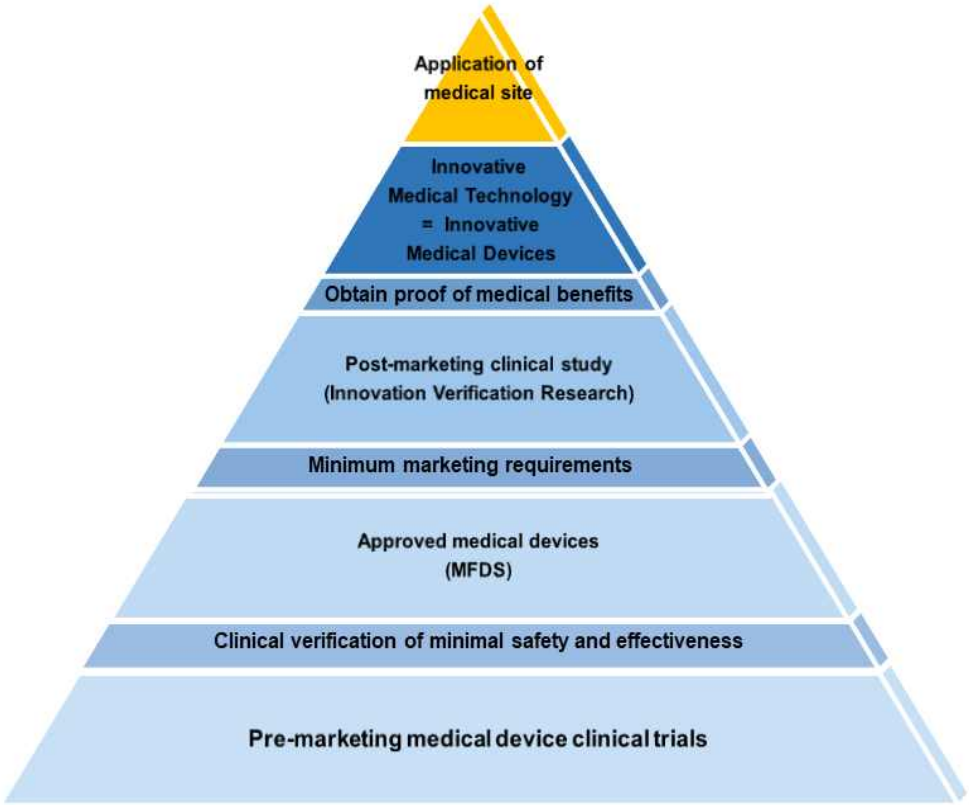

Figure 7. Policy Direction of the Innovative Medical Device Designation System

4.2. Subject to special case application

The provisions for designating innovative medical device groups under Article 20 of the Medical Device Industry Act establish the basis for considering innovative medical devices as subject to separate compensation as special cases. The Medical Device Industry Act establishes that the prerequisite for designating innovative medical devices must correspond to the technology included in the innovative medical device group announced by the MOHW. Therefore, in the case of medical technology related to medical devices, the policy must be unified and operated as the innovation target to maintain consistency in related policies.

Designating innovative medical device groups is announced after deliberation and a resolution by the Medical Device Industry Promotion Committee per the Medical Device Industry Act. The committee comprises the Minister of Health and Welfare, ex officio (chairman), the MFDS, vice-ministerial-level public officials of related central administrative agencies, and commission members commissioned by the chairman among those engaged in industries, academia, and research institutes with extensive knowledge and experience in the medical device industry. Since enforcing the Medical Device Industry Act in 2020, commissioned members include the head of the Health Insurance Review and Assessment Service, in charge of health insurance and nHTA, and the head of the Korea Health and Medical Research Institute. Therefore, policy consultations regarding the innovative medical device special system are possible because innovative medical device groups and devices are designated, and a legal committee for consulting between related ministries and institutions has been established for applying policy special cases.[2]

Additionally, the innovative medical device group may determine whether to extend the designation through reevaluation every three years following Article 20 of the Medical Device Industry Act. The innovative medical device group may be canceled if the technology environment changes and the target of past special cases are considered insufficient due to the generalization of technology and clinical verification at present. If the innovative medical device group's designation is canceled, the innovative medical device included in the relevant technology group may be automatically canceled, and the applications of related special cases may also be terminated. Therefore, a legal safety device has been prepared to limit the special period and review suspension if necessary for separate compensation for medical benefits involving financial investment. Additionally, since a newly emerging area can be added when reevaluating the innovative medical device group, prompt policy reflection is possible after committee deliberation, even if the special application is necessary for a new technology(Table 16).

Table 16. Designated Model of the Innovative Medical Device Group

Category	2020	2023	2026	2029
A	◎	◎	Universalization (Cancelation)	
B	◎	◎	◎	Universalization (Cancelation)
C	◎	◎	◎	◎
D	◎	◎	Absence of innovation (Cancelation)	
E	Early study (Not designated)	Early study (Not designated)	◎	◎

The current innovative medical device group classifies the definition of innovation according to the policy objectives. Regardless of whether the high-tech group supports the rapid market competitiveness of new technologies such as AI and robots or the technology subject to medical device application, medical benefits are expected to be clear when using the medical device, the medical innovation group, and the existing technology. The areas that can secure medical benefits and short-term markets through performance improvement are classified into four systems to define innovation, regardless of marketability: technological innovation and public service groups.

This is due to the lack of policy effectiveness for designating innovative medical devices, in addition to the integrated screening special system. Two high-tech medical device groups are targeted for integrated screening. There are no direct special cases other than in the licensing stage, the effect of corporate promotion (investment attraction) under the government's designation of innovative medical devices, and using additional points for participation in government tasks for each project. In the case of software medical devices, in addition to the integrated screening special case system, the software manufacturer certification system and some special cases can be applied at the licensing stage per the Medical Device Industry Act; thus, many innovative medical devices are designated through general screening.

When considering the purpose of introducing technology innovation groups other than high-tech groups at the time of classifying innovative medical device groups, products in areas that lead the domestic medical device industry are generally included in the technology innovation group. These products have already created the market based on the general original technology and will likely expand the market through technological innovation.

Most small- and medium-sized companies that lead the domestic medical device industry are included in this field. The technology innovation group, where most second-class products are applied, has significant issues at the health insurance application rather than the licensing stage. Surviving competition with emerging countries such as China, which enters the market with cheap labor costs and mass production by copying products of simple global companies, is difficult. Thus, a policy direction that induces technological innovation in the field to strengthen the domestic medical device manufacturing base is established as an innovative medical device designation target. As the special provisions related to health insurance have been deleted from the legislative process, only companies that want to use designating innovative medical devices for public relations purposes rather than providing direct health benefits receive designation through preparation.

In summary, the targets for designating medical innovation groups are those cases that meet the innovation requirements under the Medical Device Industry Act among the targets of nHTA. However, if a subject of nHTA is designated as an innovative medical device, special cases in the separate nHTA and health insurance stage are not applied; thus, designation is ineffectiveness. The public interest medical group is in a similar situation.

At the time of legislating the Medical Device Industry Act, the Ministry of Food and Drug Safety eas responsible for designating innovative medical devices. However, designating innovative medical device groups, a prerequisite for designating innovative medical devices, was assigned to the MOHW. This structure was determined by the MOHW after the special case of approval by the Ministry of Food and Drug Safety to apply special cases related to separate health insurance compensation related to the actual distribution of medical facilities under the MOHW.

However, as the nHTA and health insurance special provisions of innovative medical devices are deleted in the legislative process of the Medical Device Industry Act, designating innovative medical device groups under the enacted law is considered a regulation in designating innovative medical devices. Nevertheless, the innovative medical device group provisions were was legislated with limitations on special cases for designating innovative medical devices in terms of the industry. Still, it can be seen that the legal basis has been maintained so that the MOHW, in charge of related policies, can be involved in linking the special health insurance system through future legal and regulation revisions. An example of this policy is the integrated examination system for innovative medical devices.

Overall, the Medical Device Industry Act unified the definition of "innovation" in designing the medical device health insurance special application model into the innovative medical device group. The final application target was an innovative medical device subject to an integrated examination track.

4.3. Special application of medical care benefits

The degree of innovation was classified as follows for the special application of health insurance benefits for innovative medical devices. There are two conflicting perspectives, whether “innovation” is an innovation of technology applied to simple medical devices or whether the final goal is to improve medical effectiveness. Since designating an innovative medical device after clinically verifying all the possible high-tech medical effects in the absence of sufficient evidence for actual use does not meet the purpose of introducing the system, technologies notified as designated targets through the Medical Device Industry Promotion Committee are classified as designated targets; however, in applying health insurance, the types are subdivided as follows. As suggested in Table 17, innovation attributes were classified as medical and technical. Therefore, technical attributes were classified into two categories: improvements to existing technology and application of the first technology, whereas medical innovation was classified into three stages: treatment efficiency, safety and effectiveness improvement.

Table 17. Innovative Judgment Indicators

Type of innovation	Improvement of existing technology	First Technology Application
Improved healthcare efficiency	A	B
Existing medical technology Improvement	C	D
Replacement of existing medical technology	E	F

First, medical devices corresponding to Group A included in the first stage in the innovation determination index of innovative medical devices are classified as separate compensation except for simple medical expediting and improving patient benefits, regardless of their technical properties. This type is classified as a subject of the general examination of innovative medical devices. After designating innovative medical devices, it supports securing evidence through special licensing cases and preferential support projects for innovative medical devices without considering the connection with applying special health insurance cases. In the case of Group B, even if it is necessary to verify safety and effectiveness as a technology included in the high-tech group, medical benefits can be improved. Still, separate compensation is immediately considered in consideration of R&D efforts. However, linking the current integrated examination and innovative health technology assessment is considered depending on the selection of the developing company.

The second stage comprises groups C and D, corresponding to the existing technology in the case of group C, but with having improved safety and effectiveness through medical device performance improvement. If the medical device is not designated as an innovative device, it is applied as a separate compensation special case. An example of this type is Company L's medical device; although it was designated as an innovative medical device technology innovation group, calculating it separately was impossible because it secured its clinical basis after certification, apart from the system for designating innovative medical devices. The AI diagnosis assistance SW is an example of group D. Regarding applying the new technology, it could have been classified as a target for nHTA; however, the high-tech group medical device judged by existing technology is the target, and the innovative health technology assessment is currently being applied to innovative medical devices, despite its restriction to artificial intelligence/digital technology. Therefore, it is suggested that it apply a separate compensation special case for the

technology group. This study aims to foster a policy area to create a market immediately when considering separate compensation, a major target for the special application of innovative medical device health insurance benefits.

Groups E and F are innovative medical devices that replace existing medical technologies and support separate compensation for benefits before nHTA, regardless of whether advanced technologies are applied. The third-stage technology group is subject to nHTA, and it is possible to apply temporary nonbenefits after licensing through existing evaluation deferrals and special cases of innovative health technology assessment. Therefore, when a developing company makes the selection, if there is an existing similar medical practice, it supports the salary in the relevant medical treatment category and proposes a special case for medical treatment that establishes additional benefits. Currently, health insurance medical benefits do not apply to patients for the same medical purpose if there is an existing benefit treatment. This limits the indiscriminate increase in benefits, which can also be interpreted as limiting beneficiaries' medical options. Therefore, when selecting an innovative medical device, which is a limited area, a plan is applied to innovative medical devices in which the beneficiary is compensated for the medical treatment fee and pays only additional costs as a benefit (Table 18).

Table 18. Application of Special Cases for Health Insurance by Innovation Type

Group	Definition	Innovative Medical Device Group	Application of Special Cases
A	- Medical devices that improve the technology applied to existing products to increase the convenience of care for medical staff/patients and increase the efficiency of the medical environment	Technology Innovation	-
B	- Medical devices that increase the efficiency of the medical environment by applying advanced technology to increase the convenience of medical staff's treatment	High-tech	-
C	- Medical devices that improve the safety and effectiveness of medical staff/patients in the existing medical practice category by improving the technology applied to existing products	Technology Innovation	○
D	- Medical devices that improve the safety and effectiveness of medical staff and patients by applying advanced technology	High-tech	○
E	- New medical technology in areas where there is no alternative treatment or alternative treatment by improving the technology applied to existing products	Medical Innovation	○
F	- Medical devices that have significantly improved the safety and effectiveness of actual medical practice by applying advanced technology	High-tech + Medical Innovation	○

4.4. Separate Compensation System by Type of Innovative Medical Device Group

4.4.1. Expanding the scope of the integrated examination of innovative medical devices

Before applying separate compensation special cases, the scope of the current integrated examination of innovative medical devices must be expanded from the two middle categories of AI, big data, digital, and wearable technology groups, to the entire innovative medical device group. For safety reasons, the current integrated review targets only two noninvasive areas, considering the scope of allowances for separate health insurance compensation and special cases for evaluating innovative medical technology. Expanding the special system to the entire innovative medical device group requires readjusting the target of “innovation” from the perspective of licensing–nHTA–health insurance. This entails an overall redesign of the innovative medical device group considering the health insurance special system at the time the innovative medical device group is reevaluated in 2026.

4.4.2. Strengthen separate compensation for medical and industrial innovation

Applying some special cases to the high-tech group is necessary to classify the innovative medical device group to foster the domestic innovative medical device industry; however, the overall direction should be considered based on the medical innovation of the innovative medical device, considering separate compensation. Various institutional improvements related to high-tech groups are continuously promoted; however, the government’s support plan for technology targeting the existing technology innovation group, which occupies the entire market, is insufficient. A policy is also needed to foster innovative medical devices targeting technology innovation groups to produce an immediate market response from an industrial perspective. Therefore, the basic target of separate

compensation presented in this paper considered compensation based on medical rather than technical innovation. Through this, the current integrated screening system framework considers separate compensation by raising existing technologies to the status of new medical technology through separate screening. However, it is suggested that the method of linking existing technologies to innovative health technology assessment be improved.

4.4.3. Improvement of the compensation system and decision processing period for each action/therapeutic material

The group of innovative medical devices includes medical devices included in the performance fee and those belonging to therapeutic materials that can utilize the separate compensation system. Therefore, it is necessary to consider applying separate compensation special cases based on the type of health insurance care benefit determination. First, medical devices, software, in vitro diagnostic medical devices, and therapeutic materials operate under an additional benefit system to the existing performance fee if there is an existing similar activity fee. The current temporary benefit (selective benefit) system that transfers the benefits burden to patients is improved by reducing the financial burden of health insurance. In the case of patients who are beneficiaries, even when choosing medical treatment using innovative medical devices, if there is an existing similar medical fee, the relevant activity fee can be covered by health insurance. Additionally, a positive benefit determination method is introduced and negotiated with the innovative medical device company to determine the additional benefit or selective benefit. In the case of therapeutic materials, an institutional mechanism reviews whether to apply separately to determine therapeutic materials. Therefore, when designated as an innovative medical device, it is proposed to apply a separate calculation as a special case.

In the case of performance fees for existing technologies, up to 5% of additional benefits are applied for medical devices that have undergone an integrated assessment of innovative medical devices other than AI, referring to the policy model of additional benefits of 1% on average applied to the current AI diagnostic assistance field. In the case of the current AI field, nonpayment tracks can be selected, and in this case, up to 30% can be added to the performance fee. Thus, it is possible to select an additional benefit within 10% or nonpayment within 10–30% depending on the medical device. Currently, existing performance fees subject to add-on should be paid according to the established salary/payment decisions.

In reviewing the additional cost of therapeutic materials, a decision on whether to calculate them separately according to the “Criteria for Adjustment of Determination of Action and Treatment Materials” must be decided in advance. Therefore, companies developing innovative medical devices should be selected for separate calculation regardless of whether they have existing or new medical technologies. After separate calculations, separate compensation up to 100% for the therapeutic material valuation can be made. There is an additional 5% for innovative medical devices considering technology development efforts. It is believed possible to consider introducing a special system similar to therapeutic materials according to the case where the current AI software is subject to integrated examination. Because this was considered existing technology and was applied as the subject of an innovative health technology assessment, a temporary screening/benefit was applied.

Additionally, the legal processing deadline for determining health insurance benefits requires 00 days. However, it has been published that it takes approximately 861 days on average from the announcement of new medical technologies to the decision of medical care benefits due to insufficient grounds and procedures for inquiring opinions such as related academic societies. If all clinical and cost-effectiveness grounds are met to determine whether to pay, the special case for advanced adoption to be introduced into innovative medical devices is ineffective. Therefore, to prevent the policy authorities from exceeding the legal processing deadline, a plan to prioritize medical care benefits as suggested by the applicant for an undecided period within 100 days (Table 19) is suggested.

Table 19. Application of Special Cases for Health Insurance by Type

Category	Medical practice	therapeutic materials
Preexisting Medical Technology	(Benefits) Up to 5% (Screening/nonbenefits) Up to 10% to 30%	Separate calculation
New Medical Technology	Innovative Health Technology assessment	Separate calculation

4.4.4. Linkage with the innovative medical device company certification system

The MOHW operates an “innovative medical device company” certification system that certifies and fosters medical device companies in compliance with Article 10 of the Medical Device Industry Act. Although there are currently approximately 18 special cases for innovative medical device health insurance (integrated review), if the health insurance special system is implemented, the number of applications and designations for innovative medical devices through screening each application case increases, imposing a financial burden on health insurance. Therefore, a plan may be considered to limit the targets of innovative medical devices designated by certified innovative medical device companies. Currently, a special system for adding drug prices is in effect for companies certified as an “innovative pharmaceutical company” according to the Pharmaceutical Industry Act.

At the time of legislation, a plan to apply the law to “innovative medical device companies” was also considered. However, an alternative bill was prepared to apply special cases to innovative medical devices that designate individual products due to the nature of the medical devices included in the activity fee. Since passing the Medical Device Industry Act in 2020, 46 innovative medical device companies have been certified, of which 6 companies and 12 innovative medical devices are currently designated as innovative medical devices. However, innovative medical device companies are an alternative when it is difficult to apply special cases directly to innovative medical devices because there is a gap between new certification announcements for at least two years under the Medical Device Industry Act.

4.5. Revision of related laws and regulations to introduce improvement measures

4.5.1. Measures to amend the Medical Device Industry Act

Establishing a legal basis by revising the Medical Device Industry Act is necessary to apply special cases of health insurance benefits for innovative medical devices. In the case of the current integrated examination system for innovative medical devices, the relevant notices of the two laws under the Medical Device Industry Act, "Regulations on the Procedures and Methods for Designating Innovative Medical Devices" and "Regulations on the Evaluation and Implementation of Innovative Medical Technologies," have been revised to operate at the level of procedure revisions. However, the lack of legislative grounds may limit when more active systems are introduced. Because revising related laws such as the National Health Insurance Act, the Medical Act, and the Medical Device Act is necessary to link the special system after designating innovative medical devices, operational stability of the system must be established through legislation to amend other laws and related administrative rules.

The Medical Device Industry Act does not restrict the integrated examination of innovative medical devices. However, if it is limited to the integrated examination of innovative medical devices because the lower notice stipulates related matters, revising and reflecting the matters related to the integrated examination in the higher statute are required. Therefore, the Medical Device Industry Act also considers expanding and reducing applying special cases in the future. The amendment was reviewed so the government can clearly define special cases for nHTA, including special cases for determining health insurance benefits for innovative medical devices and the current integrated examination system, as well as the targets and procedures in the lower statute.

However, amending the administrative rules of other laws based on the amendment to the Medical Device Industry Act to introduce the system is essential. However, although a declarative regulation is a legal basis to revise the relevant law to support innovative medical devices, establishing related special provisions in the Medical Device Industry Act is needed for the government to maintain a consistent policy stance in the future (Table 20).

Table 20. Amendment to the Medical Device Industry Act

Amendment to the Medical Device Industry Act
Article 24-1 (Special Cases for Health Insurance Benefits) ① The Minister of Health and Welfare may apply separate standards and procedures in determining whether health insurance benefits are eligible for medical treatment under Article 41-3 of the National Health Insurance Act for medical practices using medical devices licensed or certified as innovative medical devices and therapeutic materials licensed or certified as innovative medical devices. ② Matters necessary for separate standards and procedures under paragraph (1) shall be prescribed by the Ordinance of the MOHW.
Article 24-2 (Special Cases for nHTA) (1) The Minister of Health and Welfare may apply separate standards and procedures in evaluating new medical technologies under Article 53 of the Medical Service Act to new medical technologies that use innovative medical devices for rapid market entry of innovative medical devices. ② Matters necessary for separate standards and procedures, methods for establishing examination standards under paragraph (1) shall be prescribed by the Ordinance of the MOHW.

A related legislative example is Article 17-2 of the Pharmaceutical Industry Act (preferential treatment such as adding the upper limit of the drug). In the case of innovative pharmaceutical companies under the Pharmaceutical Industry Act, as in the integrated examination system for innovative medical devices without a legislative basis, additional special cases have been applied by establishing additional targets and criteria per Table 1 of the "Pharmaceutical Determination and Adjustment Standards." Therefore, related provisions were newly established in the 2018 Pharmaceutical Industry Act to compensate for the lack of legal basis. Global pharmaceutical companies can also be certified as innovative pharmaceutical companies; however, it is difficult to be the target due to the lack of a domestic R&D foundation. Consequently, due to issues such as red trade friction, the legislation of the relevant enforcement decree is not progressing, and preferential drug prices are being implemented at the current notification level.[64]

Applying relevant legislation to innovative medical devices can lead to normal frictions, as in the Pharmaceutical Industry Act. However, innovative medical devices under the Medical Device Industry Act include domestic manufacturing and import permits; thus, the logic of responding to related issues can be considered legislated.[65]

4.5.2. Measures to revise the criteria for determining and adjusting behavior and therapeutic materials

In applying preferential treatment to innovative pharmaceutical companies, details are established in the 「Criteria for Determination and Adjustment of Drugs」 enacted per the 「Rules on National Health Insurance Care Benefits」. Therefore, innovative medical devices must be revised in the 「Criteria for Determination and Adjustment of Behavioral Treatment Materials」, which is a sub-administrative rule of the same rule. First, in the case of actions, an “Innovative Medical Device Specialized Evaluation Committee” should be established so that detailed evaluation criteria can be determined to prepare for reviewing the recently paid fields to be expanded to innovative medical devices(Table 21).

Table 21. Amendment to the criteria for determining and adjusting behavioral therapeutic materials(Article 9)

Article 9
Article 9 (Evaluation of Care Benefits, etc.) Each professional evaluation committee shall consider medical validity, medical significance, treatment effectiveness, cost-effectiveness, the degree of cost burden of patients and social benefits in evaluating behavior and therapeutic materials under Article 11 (2) of the Standard Rules. ② Each professional evaluation committee shall evaluate the following matters, such as whether or not medical care benefits are eligible, relative value scores, upper limit amount, and out-of-pocket ratio, in consideration of paragraph (1). 1. (Omitted) 2. The Specialized Evaluation Committee on Medical Practice and Oriental Medicine and the Specialized Evaluation Committee on Digital Medical and Innovative Medical Devices shall evaluate the relative value score in consideration of the amount of work, such as the time and effort required for the action, the amount of resources such as manpower, facilities, and equipment, and the degree of risk of the action

Since medical practice is not a registration system in which prices are calculated for individual products such as drugs or therapeutic materials, it is difficult to uniformly specify the addition, such as the criteria for adding drugs. Therefore, the "Innovative Medical Device Specialized Evaluation Committee" will be established in the Health Insurance Care Benefit Determination Organization, a system of deliberation by the specialized committee. The details will be included in revising the subordinate laws and regulations under the revision of the Medical Device Industry Act, suggesting that the regulations apply mutatis mutandis in the 「Criteria for Determination and Adjustment of Treatment Materials」. Additionally, in forming the specialized evaluation committee under Article 12, Paragraph 1 of the same regulation, a plan may be considered to explicitly define the “experts recommended by the head of the Korea Health Industry Development Institute.” It is still possible to participate in the decision-making by “other cases where the Minister deems it necessary,” but it is necessary to force the participation of industry experts recommended by specialized institutions that foster related industries(Table 22).

Table 22. Amendment to the criteria for determining and adjusting behavioral therapeutic materials (Article 12)

Article 12
Article 12 (Composition of the Professional Evaluation Committee) The Professional Evaluation Committee under Article 11(8) of the Standards Regulations shall consist of approximately 400 members appointed or commissioned by the Minister by the recommendation of the following persons. 1.~4. (Omitted) 5. Experts recommended by the head of the Korea Health Industry Development Institute 6. Experts recommended by consumer groups 7. ~10. (Omitted)

In the case of previously registered separately calculated therapeutic materials, 5% can be added without evaluating the value of therapeutic materials following subparagraph 1 of the 「Criteria for Determination and Adjustment of Treatment Materials, etc」. The relevant targets include certifying new health technologies under the 「Health and Medical Technology Promotion Act」, and measures such as innovative medical devices can be applied first (Table 23).

Table 23. Amendment to the criteria for determining and adjusting behavioral therapeutic materials (Attachment 1)

(Attachment 1) Criteria for calculating the upper limit of the therapeutic materials
1. Where a product for the same purpose as the applied product included in the list of benefits and benefits of the therapeutic materials and the upper limit of benefits (hereinafter referred to as the "upper limit table")
A. Where a product applying for a decision submits one or more of the following data proving technology development efforts, an additional 5% may be added to the determined amount without complying with the valuation criteria table under item (b), for three years from the date of application.
(1) This refers to products that have been certified as new health technology (NET) under Article 8 of the Health and Medical Technology Promotion Act or have been recognized by the government for their technical skills and competitiveness, or therapeutic materials developed with government R&D support
(2) This refers to a clinical trial conducted and clinical data that are submitted at a research-oriented hospital or clinical trial center designated by the Minister of Health and Welfare, or an institution that operates a designated review committee among clinical trial institutions designated by the MFDS
(3) When designated as an innovative medical device under Article 21 of the Medical Device Industry Promotion and Innovative Medical Device Support Act

For innovative medical device therapeutic materials that require an additional price increase greater than 5% through valuation, such as new therapeutic materials, the Value Evaluation Criteria and Application Methods must be revised per the Appendix 1 of the 「Determination and Adjustment Criteria for Behavioral Treatment Materials」. The therapeutic material valuation is divided into two areas: breakthroughs and technological improvement, involving up to 100% in new breakthroughs or technological improvements and up to 50% in technological improvements. However, to obtain an additional 10% corresponding to the lowest addition rate, at least 20 points must be obtained from the valuation criteria table. The score of the technological innovation items in the evaluation criteria is up to 16 points; if the technological innovation part surpasses 20 points, and if innovative medical devices are added to the target or designated as innovative medical devices, it is possible for the Health Insurance Review and Assessment Service to separately determine eligibility based on the proposed revision of the Medical Device Industry Act (Table 24).

Table 24. Amendment to the criteria for determining and adjusting behavioral therapeutic materials (Attached Form 1)

(Attachment 1) Criteria for the valuation and application method
3. Application of the evaluation results (1) The total score is calculated by summing the scores for each evaluation item. The addition rate is calculated as follows: An additional 5% can be calculated if clinical trials are conducted at research-oriented hospitals and clinical trial centers approved by the Minister of Health and Welfare and if clinical literature is submitted. (2) Separate standards may be applied to innovative medical devices pursuant to Article 21 of the Medical Device Industry Act and pursuant to Article 24-1 of the same Act.

5. DISCUSSION

This study proposes a special case for health insurance care benefits for innovative medical devices designated by the Medical Device Industry Promotion and Innovative Medical Device Support Act in 2020. By analyzing the nHTA related to medical devices and the improvement plan for the medical care benefit registration system since 2014, separate compensation for health insurance, which the industry demands, is still insufficient. It is determined that only temporary screening benefits and benefits can be applied to some technologies. Japan's "Image Diagnosis Management Additional 3" system was compared to related overseas cases. It was found to be similar to the US's new technology transitional insurance benefit (TCET), particularly in introducing the domestic AI benefit, and to Germany's digital therapeutics benefit registration procedure. Systems similar to the cases of Japan and Germany were recently introduced in Korea. However, the introduction of TCET-level systems in the United States is still insufficient. TCET is also applied to very limited targets as a domestic medical benefit level, with no medical devices yet registered.

As a result of analyzing domestic and international systems, Korea’s health insurance system strength is its national medical security. It also restricts using new technologies whose benefits have not been found in other countries, making it difficult for the domestic medical device industry to enter the market. To solve this problem, the system has temporarily eased some technologies to be used as benefits or screening benefits through partial system improvement over a long period. However, after reviewing the introduction of the overseas benefit application system, the system was also improved conservatively, and related industries entered the market by reinforcing the clinical basis required by policy authorities when improving the system was delayed. In addition to artificial

intelligence/digital therapeutics devices, which are currently in the settlement phase, the government sought to introduce a special system for compensation for medical benefits for innovative medical devices, improving the price regulation system for each action.

To this end, the definition of innovation, which is separately defined by the Medical Device Industry Act, the National Health Insurance Act, and the Medical Act, was unified into the “Innovative Medical Device Group” under the Medical Device Industry Act. A plan was proposed to match the innovative medical device with the innovative health technology assessment target among the nHTA targets. Additionally, the ultimate innovation in the medical device industry is new medical treatment evaluation, which is a new medical practice in a conservative medical environment, the technology innovation group that improves existing technology, the public service group that interprets the public interest through innovation, and the innovative medical device group that establishes the entire medical innovation group as the category of innovation by the nHTA. Through this, a system improvement plan was derived so that innovative medical devices could be reviewed separately for medical benefits and special cases for nHTA. Implementing the improvement plan involves amending related laws. Therefore, revising the Medical Device Industry Act and amending the criteria for determining and adjusting therapeutic materials, a subadministrative rule of the National Health Insurance Act, were proposed. Further studies are needed to improve the details.

Additionally, introducing the system improvement plan requires responding to criticisms by the plan's stakeholders. First, the opposition's position was reviewed in applying special cases for health insurance benefits for innovative medical devices. The opinions of the National Assembly's public hearing statements at the time of legislation of the Medical Device Industry Act in 2018 were that innovative medical devices can be designated before receiving approval, but they cannot enter the market without first securing clinical authorization. 2) There is also a need to define innovative medical devices as a medical value rather than an industrial aspect. 3) In addition to the MOHW, a health insurance policy authority, the Ministry of Food and Drug Safety has the right to designate innovative medical devices. 5) In applying special health insurance cases, decisions on medical care benefits are determined based on cost-effectiveness, and separate special cases ignore the principle of medical benefits.

The rationale for responding to related claims is as follows. 1) Innovative medical devices can be designated before and after licensing; however, special cases for health insurance benefits are limited to only licensed innovative medical devices. To apply for the integrated examination of innovative medical devices for products designated before licensing, medical devices that have already been licensed or applied for licensing simultaneously during the application stage are targeted. The licensing process must be completed to complete the integrated examination process. 2) Looking at the innovation judgment index presented in this paper, technological innovation is also considered. However, a certain level of medical value is considered a prerequisite, and the level of simple efficiency improvement is not judged as a separate compensation special case. This matter must be discussed in detail by administrative rules such as public notices after revising related laws.

3) As the Ministry of Food and Drug Safety points out, it is possible to overcome the limitations of the existing general review system that targets limited medical devices, meeting the safety effectiveness review criteria under each law through an integrated examination after approval when designating innovative medical devices. 4) The members of the medical device industry promotion committee is currently "recommended by the Minister of Health and Welfare and related ministries among those engaged in industry and academia." However, this committee is under the current Medical Device Industry Act, which is prior to applying special cases for health insurance and nHTA. However, the provisions can be explicitly revised to include the medical community and related social organizations if necessary. Additionally, if the Innovative Medical Device Specialized Evaluation Committee is formed under the "Criteria for Determination and Adjustment of Behavioral Treatment Materials" and includes industry medical sectors, the industry, beneficiary, and medical sector interests can be fully coordinated in decision-making involving benefits for special cases.

5) It may be reasonable for drugs to choose nonbenefits after proving the cost-effectiveness and then proceed with determining benefits. However, since medical devices cannot be selected by themselves, it is difficult for companies to profit under the current system. Introducing medical devices into the market for reasons of cost-effectiveness is prevented; if they are operated under the current selective benefit system, it consequently restricts the rights of health insurance recipients. Instead of a health insurance benefit compensation for innovative medical devices, the primary method is to use it first as a nonbenefit. However, expanding nonbenefits is not consistent with the government’s health insurance policy as it transfer the cost burden to beneficiaries.

The limitation of this paper is its analysis of the additional financial requirements for health insurance that are expected when applying special cases for innovative medical devices. To calculate the health insurance financial estimate, some parts are estimated by analyzing detailed claims and amounts for each treatment for each medical practice, the price calculations for each innovative medical device, and the relative value scores for each medical practice. However, data from the Health Insurance Review and Assessment Service are limited in their disclosure concerning health insurance medical care benefits. This paper could not cover the entire medical practice; therefore, follow-up research is necessary.

Additionally, introducing an economic evaluation method is necessary to establish a reasonable, separate compensation system in the medical device field. In the case of drugs, the Health Insurance Review and Assessment Service uses the “Pharmaceutical Economic Assessment Guidelines” to determine their cost-effectiveness; however, there are limitations in applying them to medical devices included in medical practice. There is a difference in the level of evidence for clinical data submitted during the Ministry of Food and Drug Safety approval process for new drugs and medical devices; unlike drugs, medical practice will likely vary in the effectiveness of medical technology by operator. The Health Insurance Review and Assessment Service has also published a research report titled “Medical Technology Economic Assessment,” However, introducing this as a guideline has shortcomings.

Medical device innovation goes beyond simple technological advances to prove the effectiveness of medical practices by applying technology in actual clinical practice. Innovation involves diagnosing and treating diseases that have yet to be addressed with existing medical technology, patient benefits, convenience, and cost-effectiveness. Various medical values are presented as review items in determining the benefits of innovative medical devices and improving the nHTA system. However, there is no objective tool for evaluating these indicators.

The problem with the benefit decision process of medical practice is that the criteria for evaluating benefit adequacy or cost-effectiveness are unclear. Determinations on the adequacy or cost-effectiveness of benefits will be decided after committee deliberations, but no specific criteria for the data on which the judgment is based and what standards are evaluated are presented. The criteria for determining benefits that are not objectified may be less acceptable to applicants depending on the results and will burden the deliberation committee members. It may be difficult to present evaluation criteria for economic evaluation covering various medical practices uniformly. However, digital health and medical robots applying new technologies are changing the overall medical environment, not just individual medical practices. Delays due to the lack of a basis for determining benefit compensation, or introducing technology for political reasons without any specific criteria considering only industry aspects, can the add to confusion in the medical field.

Now is the time to present guidelines for objective economic evaluation methods for medical technology, even for individual medical technologies. In the case of medical device licensing review standards, the direction of comprehensive safety and effectiveness examination under the Medical Device Act is established, and details are set through notification and examination guidelines for each medical device. For medical practices, guidelines for determining benefits have been presented at the current level of AI and

digital therapeutics devices; however, it is also necessary to prepare guidelines for each behavior that contain more specific standards. If the MOHW prepares economic evaluation guidelines for innovative medical device groups, companies can predict the direction of determining the benefits of medical devices in the R&D stage for technology with great social impact.

The separate special compensation system for innovative medical devices can also be viewed as a health insurance pilot project. This is because medical devices have no means to accumulate evidence for proving cost-effectiveness except for some innovative health technology assessment targets. If the special compensation case for innovative medical devices is applied the basis for cost-effectiveness verification and objective evaluation criteria can be used through innovative medical devices. If this system verifies various technologies, a more fundamental economic evaluation and separate compensation methodology for medical technologies will be suggested by follow-up studies on the effectiveness of the advanced entry and exemption system for innovative medical devices, which goes beyond the special system for innovative medical devices.

6. CONCLUSION

To introduce a separate compensation plan, an essential factor in entering the innovative medical device market, which goes through the licensing–nHTA–benefit registration process, it was proposed that cases be reviewed for system improvement at home and abroad. The current system must be recognized as a new medical technology to receive temporary medical benefits by postponing nHTA and iHTA. Furthermore, this is only in the case of being designated as an innovative medical device among the advanced medical technology groups, which are innovative medical devices subject to the integrated examination of innovative medical devices, artificial intelligence/big data technology groups and digital/wearable technology groups. Even if classified as innovative medical devices, they can also be classified as innovative health technology assessment targets and receive temporary medical benefits (selected benefits/benefits). However, despite continuous system improvement, it is difficult to compensate for medical benefits separately if existing technologies and therapeutic materials cannot be calculated, other than specific limited technologies. In the case of AI medical devices, it took more than 5 years from the initial approval in 2018 for temporary medical benefits to be applied on December 23.

This study examined applying benefits whenever innovative medical devices with new technologies emerge and focused on the need to improve the basis of the current system, which takes a long time to register medical benefits even after licensing. Thus, the policy target medical devices is limited by analyzing the current status of system improvement and overseas cases, by combining the positions of policy authorities, the medical device industry, and civil society organizations in charge of the health insurance system, and by expanding and reorganizing the integrated screening system for innovative medical devices that can integrate the current medical device market entry regulatory procedures per the

Medical Device Act, Medical Act, and National Health Insurance Act, a plan was proposed to link applying special health insurance cases. If introducing the system becomes visible, current AI innovative medical device special cases can be considered at the designation stage by combining the review perspective, and the medical and industrial values for the safety and effectiveness of each institution. Although additional research is needed on the financial needs of health insurance, it is considered that the number of innovative medical devices subject to special cases can be flexibly adjusted by diversifying the number of technologies when designating innovative medical devices.

Additionally, amendments to related laws and notices are proposed as the basis for introducing the system. Further review is needed for details operated at the level of notice or guidelines in each law, although revising the 「Criteria for Determination and Adjustment of Behavioral Treatment Materials」 was proposed using the new ground provisions under the 「Medical Device Industry Act」to apply special cases of medical care benefits for innovative medical devices. Through this, introducing an Innovative Medical Device Specialized Evaluation Committee was proposed for separate compensation for innovative medical devices whose medical value is recognized regardless of existing technology, as well as establishing a committee dedicated to reviewing the behavior of innovative medical devices and separate calculation of therapeutic materials. Like the 「Criteria for Determination and Adjustment of Pharmaceuticals」, the basis for innovative pharmaceutical companies under the Pharmaceutical Industry Act to receive preferential drug prices, behavior and therapeutic materials were not covered by higher laws or notices other than those related to the therapeutic material valuation. Additional considerations will be needed, such as reflecting detailed additional matters concerning adding internal guidelines to the Health Insurance Review and Assessment Service.

Related civil society groups have objected due to safety concerns, but the Ministry of Food and Drug Safety is responsible for designating innovative medical devices, not health insurance policy authorities. The Innovative Medical Device Group, a target classification of innovative medical devices, is under the jurisdiction of the MOHW. Given the elasticity of the system and the public–private consultative body through the Medical Device Industry Promotion Committee that decides whether to redesignate it every three years, the system will be able to operate by collecting input from all sectors. Limiting compensation for benefits due to safety documents and effectiveness reviews of licensed medical devices may be a denial of the licensing process itself under the Medical Device Act. Compensation for health insurance benefits is believed to be due to concerns about the financial soundness of health insurance if policies restrict the spread of payments and separate compensation procedures are institutionalized for all medical devices. To solve this issue, the industry should strive to secure evidence through clinical evaluation after marketing to establish an economic assessment methodology for medical devices introduced in the market after the special treatment system for innovative medical devices. Therefore, it is hoped that the special system for innovative medical device benefits will not just be compensated for benefits, but will be established as a system that activates clinical research throughout the industry by proving the clinical basis of domestic medical device technology.

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ABSTRACT IN KOREAN

혁신의료기기 건강보험 급여보상 특례 적용 방안 도입

본 논문은 2020년 시행된 「의료기기산업 육성 및 혁신의료기기 지원법(의료기기산업법)」에 따라 지정되는 혁신의료기기를 대상으로 건강보험 요양급여 결정 시 급여보상 특례 적용 방안 도입을 위한 연구이다. 의료기기산업법 입법 당시 혁신의료기기의 시판을 위해 필수적인 건강보험 요양급여 우대에 관한 조항이 입법 과정에서 삭제되면서 혁신의료기기 지정에 따른 건강보험 요양급여 우대에 관한 법적 근거가 상실되었다. 이후 관련 법률의 고시 개정을 통해 혁신의료기기 통합심사 제도 등이 시행되어 혁신의료기술평가 제도와의 연계를 통해 일부 혁신의료기기의 한시적 비급여 적용 등 제도적 보완책이 마련되었으나, 여전히 혁신의료기기는 제품화 이후 급여 보상에 대한 불확실성이 존재하고 있다.

국내 건강보험 제도상 요양급여 별도 보상은 건강보험 재정적 부담을 수반하고, 이는 건강보험 가입자의 부담으로 이어지기 때문에 의료기기 산업계의 오랜 요구에도 불구하고 도입되는 개선책은 규제 절차적 기간 단축, 환자 본인 부담 비중이 높은 한시 비급여, 선별급여 수준에 머물고 있다. 의료기기산업법 시행에 따라 발표된 제1차 의료기기산업 종합계획(2023～2027)에서도 ‘혁신급여 도입’ 정책 과제를 발표하였으나, 현재까지 관련 정책 도입은 지연되고 있는 실정이다. 이에 본 논문에서는 그간의 건강보험, 신의료기술평가 등 의료기기의 보상과 관련된 정책을 분석 해보고 제도 도입이 5년 차에 접어든 혁신의료기기 지정 제도 운영 현황과 한계점을 분석하여 혁신의료기기 지정제도와 건강보험 요양급여 특례 연계를 위한 개선 방안을 도출하였다.

이를 위해 우리나라의 인허가 이후 건강보험, 신의료기술평가의 제도적 배경 및 관련 제도개선 경과를 분석하였다. 그리고 혁신의료기기 관련 국외 제도 도입 현황을 분석하여 현행 제도의 한계점과 개선 과제를 도출하였다. 의료기기분야 건강보험 급여 보상 특례 제도 도입에 있어 검토되어야 할 건강보험 재정 부담을 고려하여 특례 적용 대상을 혁신의료기기를 대상으로 한정하는 방안과 혁신의료기기 지정 대상이 되는 혁신의료기기군의 유효기간, 재평가 제도의 운영 방안을 제시하여 퇴출기전과 새로운 기술을 수용할 수 있는 제도를 검토하였다. 이를 위해 기 운영 중인 혁신의료기기 통합심사 제도를 확대하여 건강보험 특례제도와 연계하는 방안을 제시하였으며, 기존 신의료기술평가 대상뿐만 아니라 기존기술에 포함되는 혁신의료기기군 중 기술혁신군, 공익의료군까지 범위를 확대하여 제안하였다. 또한, 기존기술에 대한 별도 보상 기전과 별도산정이 불가능한 치료재료의 별도 산정 특례도 고려하여 제도개선안을 제안하였다. 종합적으로 의료기기산업법 및 국민건강보험법 관련 「행위 치료재료 등의 결정 및 조정 기준」의 개정안을 연구의 결과로 제시하였으며, 본 제도 개선 방안이 단순히 급여를 보상받는 제도에 머물지 않고, 국내 의료기기의 기술력을 임상근거로 입증하여 산업 전반에 임상 연구를 활성화하는 제도적 근간이 되길 기대해 본다.

핵심되는 말: 혁신의료기기, 건강보험, 신의료기술평가, 요양급여 별도 보상