Recommendations from the Study Group on the State of Insurance Reimbursement of Medical Technology, Anticipating Advances in Digital Health (Abbreviation: AI and Digital Health Study Group)

August 2020

公益財団法人
医療機器センター

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Executive Summary

This research project aims to provide innovative medical technology from Japan to citizens and patients ahead of the rest of the world, amid intensifying global competition in the development of digital health including AI. It offers proposals regarding the future state of insurance reimbursement of medical technology in anticipation of advances in digital health, in order to raise the predictability of insurance reimbursement, which is an exit theory for development investment required by many participating companies, and to encourage further motivation by companies toward research and development.

It is a response to the fact that there have still been no discussions held on insurance reimbursement of medical technology related to digital health, which is considered to be the most important issue for companies when engaging in commercialization, even as the promotion of research and development and the arrangement of environments related to digital health in Japan are proceeding, and the handling of laws such as the Medical Practitioners Act and the Pharmaceutical and Medical Device Act is being clarified.

With consideration for the characteristics of digital health, this study group has concluded over its study sessions that insurance reimbursement of medical technology related to digital health must include mechanisms to evaluate the outcomes brought about by the applicable technology in comprehensive evaluations.

This proposal differs in concept from the current evaluation system based on the amount of work, which focuses on structure assessments as external criteria of systems for providing people and goods, and process assessments as evaluations of the content of implemented medical treatment and care.

In addition, medical technology related to digital health is well suited to outcome assessments due to its high compatibility with the collection of outcome data. This makes it possible to actively evaluate improvements in the quality of medical care resulting from medical technology related to digital health, and effects for the reduction of medical care expenses achieved through significant savings of medical resources and shortened times for service provision, as well as to perform re-evaluations after a certain period of time has passed.

For this reason, in addition to the knowledge gained in the past through the evaluation of medical devices and technology, medical technology related to digital health inevitably requires specialization and specialists from other different fields, so it will be necessary to establish a new specialized organization in the Central Social Insurance Medical Council (CSIMC). It will also likely be necessary to create new remuneration items based on medical technology related to digital health, in order to clearly distinguish between medical technology related to digital health which is and is not evaluated by medical insurance.

This report summarizes these matters as five recommendations on the state of evaluation of medical technology related to digital health.

We hope that the results of this study will serve as a foundation for studies by other related parties, and that it will promote further discussions so that a system can be formed and established.

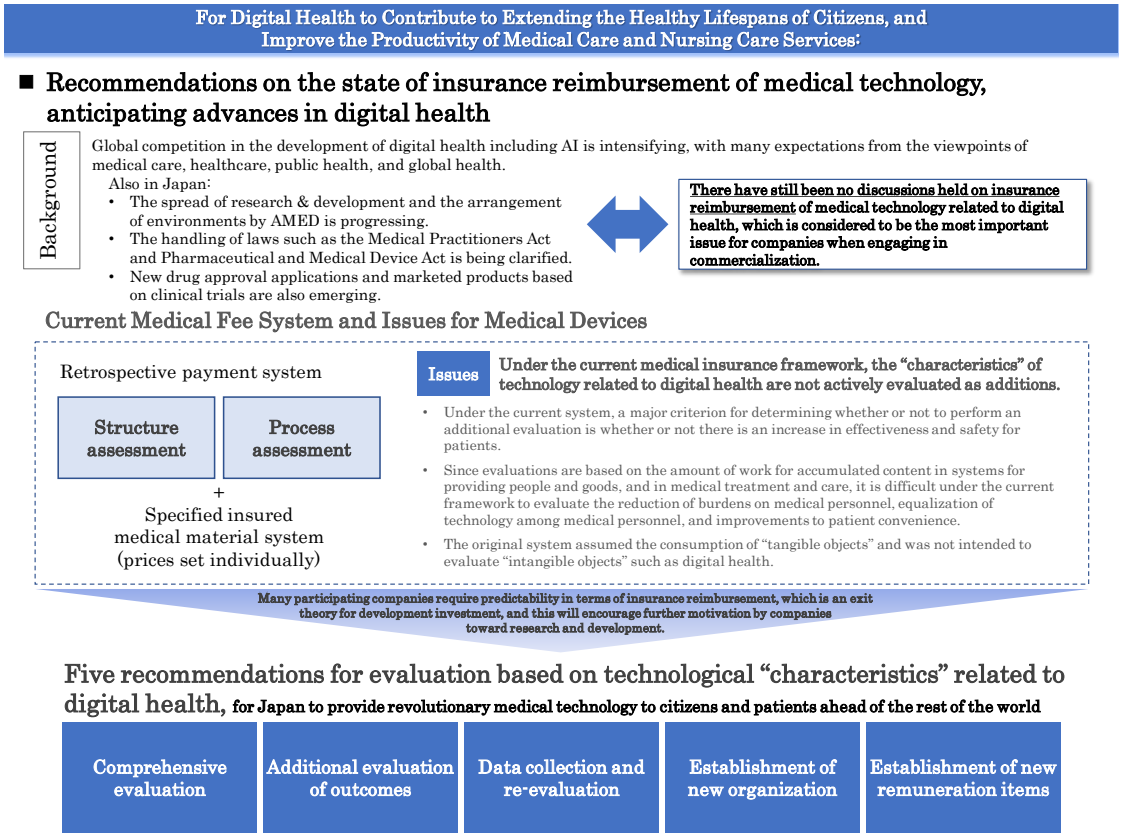

Figure: Recommendations from the AI and Digital Health Study Group (Summary)

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List of Members of the Study Group on the State of Insurance Reimbursement of Medical Technology, Anticipating Advances in Digital Health
(Abbreviation: AI and Digital Health Study Group)

⊙ indicates the Study Group Chairman (Japanese syllabary order)

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The "Study Group on the State of Insurance Reimbursement of Medical Technology, Anticipating Advances in Digital Health" (abbreviated as "AI and Digital Health Study Group") is implemented as an independent research project by the Japan Association for the Advancement of Medical Equipment. Under this project, study requests were made to the expert individuals indicated above, and the results of the study by the study group were compiled as a report, with the Medical Device Strategy Institute affiliated with the Japan Association for the Advancement of Medical Equipment serving as the Secretariat. The opinions and other information in this report do not represent the opinions of individual committee members.

Meetings of the AI and Digital Health Study Group

1st Meeting: November 12, 2019 (Tuesday)

2nd Meeting: January 28, 2020 (Tuesday)
[Hearing of opinions]
Kohta Satake, Representative Director & CEO, CureApp, Inc.
Sho Okiyama, President & CEO, Aillis Inc.

3rd Meeting: February 25, 2020 (Tuesday)
[Hearing of opinions]
Yuki Shimahara, CEO, LPIXEL Inc.
Masashi Misawa, Digestive Disease Center, Showa University Northern Yokohama Hospital

4th Meeting: March 13, 2020 (Friday)

5th Meeting: July 2, 2020 (Thursday)

1. Introduction

With the progress of IT, movements toward social implementation of the digital health field, which uses and applies elements such as apps, wearable devices, connected devices, artificial intelligence (AI), and big data[1], are becoming more active in the medical care and health fields.

Even in Japan, in documents from the Minister of Health, Labour and Welfare at the 16th Future Investment Conference held on May 17, 2018, as "Initiatives by the Ministry of Health, Labour and Welfare to Build a Next-Generation Healthcare System", it is stated: "In anticipation of the 100-year life, the efficient provision of high-quality healthcare services by methods such as the application of big data will be essential. It is believed that this will improve the productivity of medical care and nursing care services and extend the healthy lifespans of citizens. ".

The "2020 Basic Policy for Economic and Fiscal Management and Reform: Overcoming the Crisis and Looking Toward a New Future" (otherwise known as the "2020 Basic Policy"), which was decided on by the Cabinet on July 17, 2020 and looks toward a new future in the post-coronavirus era, stated that reform requiring a period of 10 years will be advanced in a sweeping move by the concentrated investment and implementation of digital transitions which will become the driving force for the creation of the "new normal", and its related

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[1] Although a wide range of organizations has proposed definitions and interpretations of digital health, at this time there are no consistent interpretations or opinions on it. Therefore, this study group did not focus on discussing the definitions and interpretations of digital health, but instead simply took a broad viewpoint toward the definitions and interpretations given by each organization. Some definitions and interpretations of digital health by various organizations are introduced below.

U.S. FDA: The broad scope of digital health includes categories such as **mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine**. These technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional care settings. From mobile medical apps and software that support the clinical decisions doctors make every day to artificial intelligence and machine learning, digital technology has been driving a revolution in health care. Digital health tools have the vast potential to improve our ability to accurately diagnose and treat disease and to enhance the delivery of health care for the individual. Digital tools are giving providers a more holistic view of patient health through access to data and giving patients more control over their health. Digital health offers real opportunities to improve medical outcomes and enhance efficiency. (https://www.fda.gov/medical-devices/digital-health)

U.K. NICE: **Apps, programmes and software used in the health and care system. They may be standalone or combined with other products such as medical devices or diagnostic tests.** (from "Evidence standards framework for digital health technologies", https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies)

WHO: The field of knowledge and practice associated with the development and use of digital technologies to improve health. **Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart-devices and connected equipment. It also encompasses other uses of digital technologies for health such as the Internet of things, artificial intelligence, big data and robotics**. (from "Draft global strategy on digital health 2020–2024", Draft 22nd March 2020). The WHO has also published a detailed classification method for digital health according to the "Classification of Digital Health Interventions v 1.0" (2018).

Lancet Digital Health: The Lancet Digital Health publishes important, innovative, and practice-changing research on **any topic connected with digital technology in clinical medicine, public health, and global health**. (https://www.thelancet.com/landig/about) First published in May 2019.

HIMSS: In "Digital Health: A Framework for Healthcare Transformation" (March 2, 2020), 22 definitions and interpretations of digital health are introduced from a variety of documents and materials, showing the diversity of digital health concepts and perspectives.

environmental improvements (the "Digital New Deal"). It is believed that the promotion of digital transitions through this Digital New Deal will contribute to solving many issues faced by Japan, and will support its future economic growth. It is explained that it will not only be the introduction of new technology, but also changes to the state of systems, policies, and organizations in accordance with them, or in other words the DX (digital transformation) of society as a whole, which will be the driving force behind the "new normal".

Currently, with many companies at the development stage regarding medical technology related to digital health including AI, a large number of participating companies require predictability[2] of insurance reimbursement, which is an exit theory for development investment. The purpose of this study group is to offer proposals regarding the state of insurance reimbursement of medical technology, in anticipation of advances in digital health to encourage further motivation by companies toward research and development. In a narrow sense, these proposals will support industries moving forward in the field of digital health including AI, but in a broader sense they aim to contribute to "extending the healthy lifespans of citizens" and "improving the productivity of medical care and nursing care services".

For this purpose, the "Study Group on the State of Insurance Reimbursement of Medical Technology, Anticipating Advances in Digital Health" ("AI and Digital Health Study Group") was established in the Japan Association for the Advancement of Medical Equipment. Between November 2019 and July 2020, five study sessions, and exchanges of opinions with development-related personnel invited to participate, were held by a research council composed of experts, where the state of insurance reimbursement of medical technology related to digital health was discussed with a view to providing innovative medical technology to citizens and patients ahead of the rest of the world.

[2]Predictability: Since insurance reimbursement of medical devices and technology is a matter for administrative decision rather than independent decision by companies, it is categorized as an external factor to companies. In the industrial world, regarding insurance reimbursement of new products and technology, predicting the probable answers to questions such as whether they will be subject to reimbursement in the first place, when their decisions will be made and according to what types of rules, what approximate prices they will have, and what approximate points they will have if there are technical fees, is an extremely important factor in making investment decisions. Companies therefore require predictability in order to continue to provide even more outstanding medical technology.

2. Current circumstances surrounding digital health in Japan

2.1. Low birthrate combined with aging population, and labor shortage

Japan has maintained a high standard of medical care since the establishment of the Universal Healthcare System in 1961, achieving an average lifespan among the highest in the world and an extremely low child mortality rate. At the same time, however, Japan's society is entering a population decline as its low birth rate and aging population are proceeding at a rapid rate with no equal in other countries.

Under these conditions, a decrease in the working-age population will lead to the grave problem of a labor shortage. At medical care (nursing care) workplaces in particular, various issues such as a shortage of medical personnel, uneven regional distribution, uneven distribution by medical departments, and work style reforms, are being compounded on each other (Figure 1).

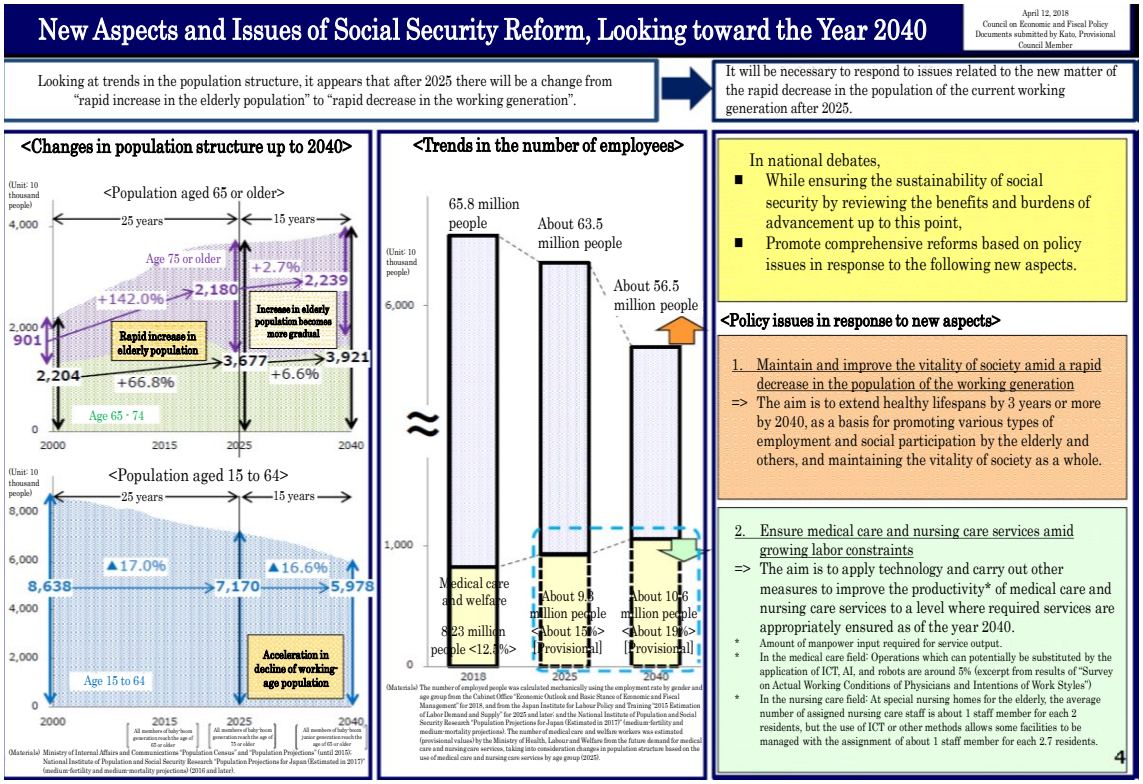

Figure 1: New Aspects and Issues of Social Security Reform, Looking toward the Year 2040

Source: Materials from Ministry of Health, Labour and Welfare, "2nd Social Security and Work Style Reform Headquarters, Looking toward the Year 2040" / Materials submitted by Kato, Provisional Member of Council on Economic and Fiscal Policy, April 12, 2018

2.2. Debates over rising medical care expenses

Looking at the medical insurance system, income growth has stagnated since the collapse of the bubble economy, as medical expenses are increasing at a rate exceeding the growth of the GDP in combination with the advancement of medical care and the aging of society. Under these circumstances, discussions on

・ Increasing the sustainability of the medical insurance system itself, and

・ Overcoming the contradictory issues of "improving the quality of medical care" and "providing efficient medical care", are continuing.[3]

2.3. Expectations for technological innovation to achieve economic growth and fiscal consolidation

The "2019 Basic Policy for Economic and Fiscal Management and Reform" (otherwise known as the "2019 Basic Policy") decided on by the Cabinet on June 21, 2019, includes content stating that accelerating the realization of "Society 5.0"[4] will be required in order to both realize sustainable and inclusive economic growth, and achieve fiscal consolidation.

It also states that reform measures toward social security for all generations should include the assurance of effective and efficient medical care and welfare services which apply technological innovations, and mentions encouraging the utilization of ICT, robots, AI, and other technology at medical care and nursing care workplaces.

2.4. Expectations for digital health by the Ministry of Health, Labour and Welfare

In its "Social Security and Work Style Reform Headquarters, Looking toward the Year 2040", the Ministry of Health, Labour and Welfare aims to improve the amount of services that can be provided per unit time by at least 7% for physicians, in order to improve the productivity of medical care and welfare services.

The specific reform items presented in the report include promotion of the practical application of technology such as robots, AI, and ICT, online medication guidance, and a review of the remuneration system to encourage efforts for greater workplace efficiency (introduction of performance evaluations, etc.). It is expected that the future progress of digital health will become a major driving force for such reform (Figure 2).

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[3] For example, the Ministry of Health, Labour and Welfare's "Social Security and Work Style Reform Headquarters, Looking toward the Year 2040", etc.

[4] According to the website of the Prime Minister's Office, "'Society 5.0' refers to the 5th new type of society in the history of mankind, continuing on from a 'hunting society', 'agricultural society', 'industrial society', and 'information society'. By incorporating advanced technology such as IoT, robots, artificial intelligence (AI), and big data into various industries and our social lifestyle, we aim to realize Society 5.0, which will be a new type of society that simultaneously balances economic advancement with the resolution of social problems. " https://www.kantei.go.jp/jp/headline/seicho_senryaku2013.html Access date: July 1, 2020

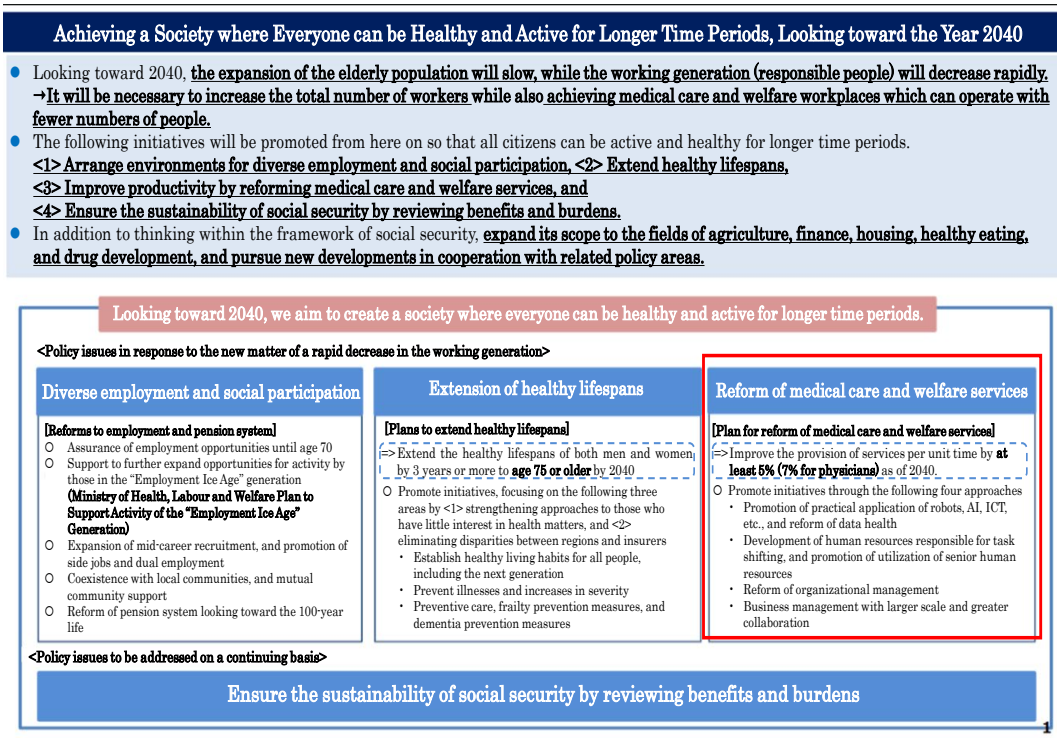

Figure 2: Achieving a Society where Everyone can be Healthy and Active for Longer Time Periods, Looking toward the Year 2040
Source: Materials from Ministry of Health, Labour and Welfare, "2nd Social Security and Work Style Reform Headquarters, Looking toward the Year 2040"

2.5. Industry trends related to digital health, and issues for its commercialization

The size of the global digital health market is estimated to be greater than US $100 billion (approximately 10 trillion yen) as of 2020[5], and a high compound annual growth rate (CAGR) of 12%[6] is expected over the period from 2018 - 2023.

As of February 2019, the global status of approval for medical device programs using AI consisted of 30 items approved in the United States and 3 items in Korea. It has also been reported that companies in India, China, the Netherlands, and Austria[7] are moving toward commercialization of products.

Specifically, in the United States, an AI-driven predictive monitoring system for low blood pressure was approved[8] in March 2018, to provide information to physicians of the possibility for drops in blood pressure to occur in patients during surgery, before they actually occur. In addition, the first AI medical device to automatically detect moderate or

[5] Roland Berger, "Think Act No, 104: Identifying the Essence of Digital Health" (March 2015)
[6] Global Digital Health Outlook, 2020, Frost & Sullivan(August 2019)
[7] Report from Evaluation Workgroup in Artificial Intelligence Field, FY2018 Project to Create Next-Generation Evaluation Indicators for Medical Devices and Regenerative Medicine Products, National Institute of Health Sciences (2019. 4)
[8] https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160044.pdf *This is not a type that can continue learning on its own after being placed on the market to change its performance.

higher diabetic retinopathy without the need for diagnosis by a physician was approved[9] in April 2018, and a game-based digital therapeutic device that can improve the attention function of children with ADHD was approved[10] in June 2020. From a broad perspective of digital health which includes integration with robotics technology, robotic systems to remotely deliver and operate instruments such as catheters during percutaneous coronary intervention (PCI) have been approved in addition to surgical support robots that have already established themselves in medical care, and social implementation of digital health is expected to proceed rapidly in the future.

At the same time, medical device industry organization AdvaMed is engaged in activities which address the future market expansion of digital health, such as launching an initiative to provide participating companies with a centralized online source which summarizes information on digital health as a "Center for Digital Health", and establishing a group known as the "Digital Therapeutics Alliance"[11] in 2017.

Meanwhile, in Japan the number of pharmaceutical consultations with the Pharmaceuticals and Medical Devices Agency (PMDA) regarding the marketing authorization (or approval) of medical devices developed using AI has been increasing year by year (Figure 3). As strong motivation toward development in this field is being seen in companies, an endoscopic diagnostic imaging support program was approved[12] on December 6, 2018 as the first medical device equipped with AI functions. Since then, movements toward industrialization of this field have been growing more active, including the approval[13] of a cerebral aneurysm diagnosis support program from MRA on September 17, 2019 as a medical device equipped with AI developed through deep learning, and the approval[14] of a smoking cessation treatment support system on August 21, 2020 as the first domestic application to treat nicotine dependency.

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[9] https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm604357.htm *This is not a type that can continue learning on its own after being placed on the market to change its performance.

[10] https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-game-based-digital-therapeutic-improve-attention-function-children-adhd

[11] The Digital Therapeutics Alliance considers Digital Therapeutics (DTx) to be "used independently or in conjunction with pharmacotherapies, medical devices, or other forms of treatment, through evidence-based therapeutic intervention using high-quality software programs to prevent, manage, or treat medical disorders or diseases, in order to optimize the outcomes of patient care and health. "

[12] Endoscopic diagnostic imaging support program for disease differentiation, Item name "EndoBRAIN Endoscopic Diagnostic Imaging Support Software", Approval No. 23000BZX00372000. *This is not a type that can continue learning on its own after being placed on the market to change its performance.

[13] Program for MR device workstation, Item name "EIRL aneurysm Medical Image Analysis Software", Approval No. 30100BZX00142000 *This is not a type that can continue learning on its own after being placed on the market to change its performance.

[14] Smoking cessation treatment support system, Item name "CureApp SC Nicotine Dependency Treatment App and CO Checker", Approval No. 30200BZX00271000

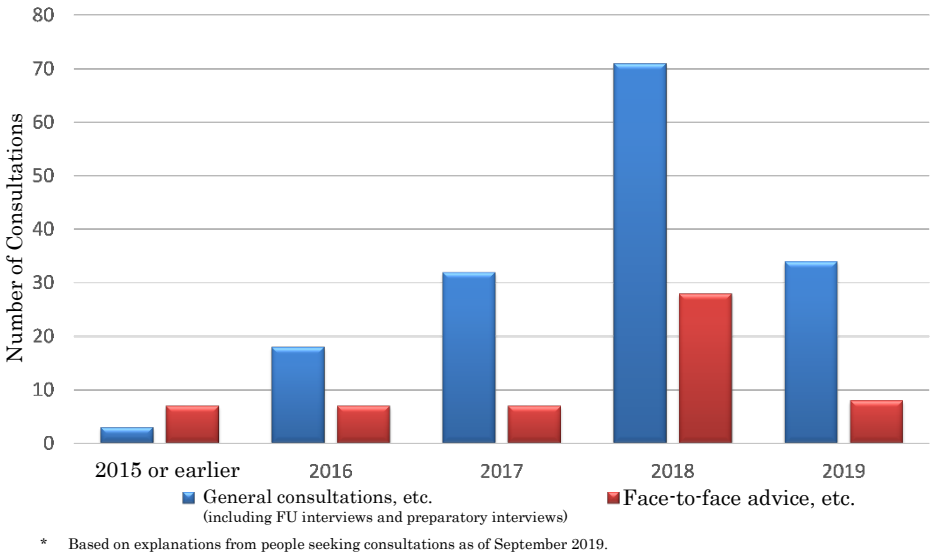

Figure 3: Consultations with PMDA on Medical Devices Developed Using AI
Source: From materials provided by Shinichi Takae, Manager, Medical Device Evaluation Department I, Pharmaceuticals and Medical Devices Agency

On the other hand, three obstacles[5] have been pointed out regarding the commercialization of digital health with expectations of progress: <1> difficulty of monetization, <2> large number of stakeholders, and <3> rapid life cycle. However, since Japan's medical insurance system is mainly considered to presume the Universal Healthcare System, it will be necessary for the government to actively carry out studies from the viewpoint of promoting digital health in the medical care field.

In addition, "Digital Health: Reforming Medical Care and Nursing Care through Innovation at the System Level", published by the Japan Association of Corporate Executives on April 24, 2015, indicates future issues consisting of reviewing the scope of application of the health insurance system and expanding private insurance, and also requires predictability of insurance reimbursement, which is an exit theory for corporate development investment.

2.6. Range of study for measures in the digital health field from the viewpoint of AI-related studies

The "Report of the Council for the Promotion of AI Utilization in Health and Medical Care Fields" and "Consortium for Accelerating the Development of AI in Health and Medical Care Fields: Organization of Discussions, and Future Directions", compiled by the Ministry of Health, Labour and Welfare on June 27, 2017 and June 28, 2019, study measures to establish infrastructure to promote AI development in fields and private companies with important priority for development. However, the main subjects of the studies are only the summarization of existing regulatory concepts, such as the establishment of an environment to collect data for development, and the clarification of handling related to laws such as the Medical Practitioners Act and the Pharmaceutical and Medical Device Act.

As a related effort, a study from the Medical Practitioners Act on providing medical treatment by applying programs that support diagnosis, treatment, etc. using AI has been summarized into statements such as "AI is nothing more than a support tool for presenting information more efficiently in sub-steps of judgments primarily made by physicians in treatment processes, and at least for the time being, the physician shall be

the main decision maker."[15] In relation to the use of programs that support diagnosis, treatment, etc. using AI and the provisions of Article 17 of the Medical Practitioners Act (Medical Practice and Medical Procedures), it also clarifies and conveys that even in cases where treatment is conducted by programs that provide support for diagnosis and treatment using AI, "diagnosis, treatment, etc. shall be mainly carried out by the physician", "physicians shall be responsible for the final judgment", and "the applicable treatment shall be carried out as a medical practice under Article 17 of the Medical Practitioners Act."[16]

As a study from the viewpoint of pharmaceutical regulations for medical devices using AI, the "2017 Issues and Recommendations Concerning Medical Diagnostic Systems and Medical Devices which Utilize AI" were summarized by the Science Committee of the PMDA on December 27, 2017. In addition, the "Artificial Intelligence Field Evaluation Workgroup" was established in cooperation with the Ministry of Economy, Trade and Industry's Project to Create Medical Device Development Guidelines, in the Ministry of Health, Labour and Welfare's Project to Create Evaluation Indicators for Next-Generation Medical Devices and Regenerative Medicine Products, from FY2017. Current ideas on the problem points and matters to be noted when evaluating the effectiveness and safety of medical diagnostic imaging support systems using AI, from the viewpoint of pharmaceutical regulations, have been summarized and communicated as the "Evaluation Indicators for Medical Diagnostic Imaging Support Systems using Artificial Intelligence Technology".[17]

On the other hand, the Japan Agency for Medical Research and Development (AMED) has for some time implemented the "ICT Infrastructure Construction and Artificial Intelligence Implementation Research Project for Clinical Research, etc." in order to construct foundations for the application of information and communication technology (ICT) at clinical workplaces, and support research and development projects to develop artificial intelligence (AI). Using medical treatment image data and instructor data collected by connecting to medical databases and accelerating the construction of AI technology infrastructure, it is promoting the development of implementable treatment support software and AI systems such as treatment support systems, and is proceeding to develop an environment that can contribute to future clinical research and AI development requests.[18] In addition, the "Medical Arts Research Project" is to be launched as a new project from FY2020. It aims to convert the knowledge and experience of medical personnel and medical technology into digital and data form, perform evaluation analysis on it, and create databases which can be used to apply ICT and AI technology to develop innovative treatment methods and practically implement new medical technology and

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[15] Organized based on surveys, etc. on medical treatment support using AI and other ICT in the FY2017 Health, Labour and Welfare Administration Promotion Survey Project Grant "Research on Medical Treatment Support using ICT such as AI" (Principal Researcher: Kazuaki Yokoyama, Assistant Professor, Department of Hematology/Oncology, IMSUT Hospital, The Institute of Medical Science, The University of Tokyo)

[16] Chief, Medical Professions Division, Health Policy Bureau, Ministry of Health, Labour and Welfare, "Relationships between the Use of Programs to Support Diagnosis, Treatment, etc. using Artificial Intelligence (AI), and the Provisions of Article 17 of the Medical Practitioners Act", Published by the Medical Professions Division of the Health Policy Bureau, 1219 No. 1, December 19, 2018

[17] Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, "Publication of Evaluation Indicators for Next-Generation Medical Devices", Published by the Medical Device Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau, 0523 No. 2, May 23, 2019

[18] Tomoaki Kuwano: Introduction to Research Project for Construction of ICT Infrastructure and Implementation of Artificial Intelligence in Clinical Research, etc., by the Japan Agency for Medical Research and Development (AMED), Pharmacia, Vol. 54 No. 9, 2018

systems for such innovative methods.[19] The spread of research and development related to digital health will be promoted to a greater extent than ever before even in Japan.

As described above, AMED has promoted research and development, improved the status of the related environment, and clarified the handling of laws such as the Medical Practitioners Act and the Pharmaceutical and Medical Device Act, but there is no evidence that detailed discussions have been carried out on the insurance reimbursement of medical technology related to digital health, which is considered to be the most important issue for companies when engaging in commercialization.

2.7. Basic viewpoint of this study group

This study group will take the above circumstances into consideration and investigate the following tasks with regard to the state of insurance reimbursement of medical technology related to digital health (including AI technology):

- Provide suggestions now, when many companies are in the development (pre-development) stage
- Increase predictability related to company commercialization strategies
- Encourage the motivation of companies toward research and development

While aiming to provide innovative medical technology to citizens and patients ahead of the rest of the world, its goals are also to efficiently provide high-quality healthcare services and extend the healthy lifespans of citizens.

[19] Materials from FY2020 Research Project Implementation Policy; Science and Technology Subcommittee, Welfare Science Council, Ministry of Health, Labour and Welfare, July 25, 2019

3. Basic perspective on evaluations of medical technology related to digital health

3.1. Subjects for studies on evaluation and premises for discussion

The subjects of study for this study group consisted of digital health including remote medicine and AI technology, focusing mainly on Doctor-to-Patient (D-to-P) medical technology[20] (in this report, the term "medical technology" is used in a broad sense, including physician procedures and medical devices, unless otherwise noted). It conducted discussions on the ideal state of insurance reimbursement with consideration for the current status of the Pharmaceutical and Medical Device Act, Medical Practitioners Act, and Health Insurance Act, as related to the state of evaluations.

Classifications made in overseas regulations and the direction of pharmaceutical regulations currently being studied in Japan were also considered. Even in discussions on the state of insurance reimbursement, studies which considered the extent of impacts (risks) that devices may have on the health status of patients and the importance of information when making judgments on information gathering, diagnosis, and treatment, were conducted. Additionally, regarding medical technology which could conceivably surpass existing concepts due to revolutionary technological innovations, discussions (and suggestions) were held with consideration for the innovativeness of such technology. Investigations were also held on matters such as the state of evaluation and on evaluation systems which would allow responses to be carried out whenever such technology were to appear.

In addition, "medical technology related to digital health" to be specifically studied was considered to be the following, which have the possibility to be developed and put on the market as soon as possible.

- Technology that enables medical personnel to diagnose and treat patients regardless of time or geographical constraints

  e.g. Online medical treatment and remote monitoring, wearable and wireless devices for chronic diseases such as cardiac failure and diabetes, etc.

- Technology that replaces or supports part or all of the processes for diagnosis and treatment performed by medical personnel

  e.g. AI diagnostic imaging and pathological diagnosis, mobile apps, digital biomarkers, support for clinical decision-making, automatic calculation of insulin doses for Type 2 diabetes, etc.

Studies were conducted with the aim of sequentially reflecting the contents of proposals (suggestions) starting from the next Revision of Medical Fees.

3.2. Current methods and issues for evaluation of medical technology

3.2.1. Evaluation method for medical devices under the Specified Medical Device System

Under the current Specified Medical Device System, medical device evaluations are divided into two classifications: comprehensive evaluation (packaged in technical fees) and evaluation based on amount of work (individual reimbursement).

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[20] Drug development using AI, etc., which was indicated as one of the six priority areas in the AI Utilization Promotion Conference, has been excluded. Devices that are not directly related to the diagnosis and treatment of patients, such as electronic medical record systems and systems to simplify administrative procedures, have also been excluded.

The basic concept of the current medical device insurance reimbursement system is according to the Central Social Insurance Medical Council's "Proposal on the Evaluation of Specified Insured Medical Materials" ("CSIMC Proposal" hereafter) from September 1993. The following are its basic principles for the evaluation of insured medical materials.

(1) Insured medical materials to be evaluated as premium for technical fee: A2 (specified package)
In cases where the medical technology that uses the insured medical material is limited to certain technologies, such as automatic stapling devices and automatic suture devices for malignant tumor surgery (other examples: ultrasonic coagulation and incision devices), and cases where insured medical materials of medical institutions, such as oxygen concentrators and oxygen cylinders, are lent to patients who are undergoing home medical care, the expenses for the insured medical materials shall be evaluated as a premium for the technical fee.

(2) Insured medical materials to be evaluated packaged with specific technical fees; A2 (specified package)
In cases such as intraocular lenses used for intraocular lens implantation, or laparoscopes used for laparoscopic cholecystectomy, where the relationship between the technical fee and the insured medical material is integral and inseparable, evaluation shall be conducted with the insured medical material included in the technical fee (other examples: laparoscope ports, electroencephalographs).

(3) Insured medical materials to be comprehensively evaluated on an average basis in terms of technical fees: A1 (package)
For insured medical materials that have a low price and a high frequency of use, and are difficult to calculate for separately from technical fees, such as tubes, sutures, elastic bandages, primary emergency coverings for skin defects, and some catheters, evaluations shall be conducted with the average of their expenses included in the technical fee. However, the technical fee shall be evaluated while including the expenses of the insured medical materials to be packaged (other examples: hypodermic needles for blood collection).

(4) Insured medical materials whose prices should be set: B (individual evaluation), C1 (new function), C2 (new function / new technology)
Items to which the evaluation methods from (1) to (3) above do not apply, or in other words, items with high prices (example: artificial heart valves) or with large market scales (examples: PTCA catheters, pacemakers) shall be subjected to separate price evaluations as "specified insured medical materials".

The system has been subsequently revised several times, and the current classifications of medical devices for the purpose of insurance coverage are as follows[21] (Figure 4).

A1 (package)	Technology utilizing the medical device concerned is evaluated by any of the items given in the medical fee calculation methods (2008 Ministry of Health, Labour and Welfare Announcement No. 59, "Calculation Method Announcement" hereafter). The medical device may be used for medical treatment provided by health insurance. Excluding items falling under A2 (specified package) or A3 (existing technology, modified). (Those not equivalent to C1 (new function) or C2 (new function / new technology))
A2 (specified package)	Technology utilizing the applicable medical device is evaluated by a specific item given in the Calculation Method Announcement. The medical device falls under any of the separately stipulated classifications of medical devices subject to specific medical fee calculation that may be used for medical treatment provided by health insurance. (Those not equivalent to C1 (new function) or C2 (new function / new technology))

[21] Chief, Health Policy Bureau, Ministry of Health, Labour and Welfare, and Chief, Health Insurance Bureau, Ministry of Health, Labour and Welfare, "Handling of insurance coverage, etc. for medical devices", Published by the Health Policy Bureau, 0207 No. 3 and Published by the Health Insurance Bureau, 0207 No. 4, February 7, 2020

A3 (existing technology, modified)	Technology utilizing the applicable medical device is evaluated by any of the items given in the Calculation Method Announcement. However, the medical device includes changes to important points in the calculation. (Those not equivalent to C1 (new function) or C2 (new function / new technology))
B1 (existing functional classification)	The applicable medical device falls under any of the functional classifications or provisional functional classifications given in the specified insured medical materials and material prices ("material price criteria" hereafter). (Those not equivalent to C1 (new function) or C2 (new function / new technology))
B2 (existing functional classification, modified)	The applicable medical device is evaluated in the functional classification or the provisional functional classification given in the material price standards. However, the medical device includes changes to important points in the definition and calculation of the functional classifications. (Those not equivalent to C1 (new function) or C2 (new function / new technology))
B3 (fixed time premium for improvement / provisional functional classification)	Technology utilizing the applicable medical device is evaluated by any of the items given in the Calculation Method Announcement. However, the Central Social Insurance Medical Council ("CSIMC" hereafter) needs to discuss the addition of a fixed time premium for improvement for the existing functional classification in the material price standards. (Those not equivalent to C1 (new function) or C2 (new function / new technology))
C1 (new function)	Technology utilizing the applicable medical device is evaluated by any of the items given in the Calculation Method Announcement. However, the CSIMC needs to discuss the establishment of a new functional classification in the material price standards.
C2 (new function / new technology)	Technology utilizing the applicable medical device (including a modified medical device) should be evaluated with the establishment of a new technical fee in the Calculation Method Announcement. The CSIMC needs to discuss the possibility of insurance coverage.

(1) Comprehensive evaluation of medical devices

The evaluation of classification A, which is a comprehensive evaluation, is based on the following concept.

Evaluation by A1 (package) is positioned as being for miscellaneous goods with high versatility, with a strong connotation of equalizing the burdens for the cost of applicable medical devices among the remuneration paid to medical institutions. Evaluation by A2 (specified package) is for cases where the connection between technical fees and medical devices is strong, and consists of evaluation of factors such as the value and performance of a medical device as part of the evaluation of technical fees.

In comprehensive evaluations like these, even if the value of a medical device increases as a result of refinements and improvements made to it, the corresponding increase in its technical fees would be addressed only by re-evaluation which is conducted once every two years at the time of Revision of Medical Fees. The flexibility and predictability of innovation evaluations will decrease because in principle, companies will not be able to become involved, and also because of the effects of the revision rate.

(2) Evaluation of medical devices based on amount of work (individual reimbursement)

Classification B, which evaluates the prices of individual medical devices, regulates the methods of price setting for so-called specified insured medical materials in detail[22], and

[22] For example: Chief, Health Insurance Bureau, Ministry of Health, Labour and Welfare, "Criteria for Calculating Insurance Reimbursement Prices for Specified Insured Medical Materials", Published by the Health Insurance Bureau, 0207 No. 3, February 7, 2020; Chief, Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare and Chief, Medical Economics Division, Health Insurance Bureau, Ministry of

is considered to have a certain degree of predictability. However, re-examination of the value of medical devices after their launch is only permitted for challenge applications[23] introduced by the FY2018 reform to the material price system. For cases other than challenge applications, prices will not be re-evaluated except for price revisions carried out in accordance with the Revision of Medical Fees, in order to adjust differences between insurance reimbursement prices and actual market prices according to the actual market price survey conducted once every two years.

Furthermore, both classifications A and B have the advantage that if technical fees are related to an item that already exists, the evaluation can basically be quickly shifted to an evaluation of medical fees if marketing authorization (or approval) can be obtained under the Pharmaceutical and Medical Device Act. However, for medical devices that require the establishment of technical fees for new medical technology whose technical fees have not been set, a certain period of time will be required until insurance coverage, and evaluations of "front-runner" companies which have established new technical fees or classifications, and of the applicable technology, are also not sufficient.

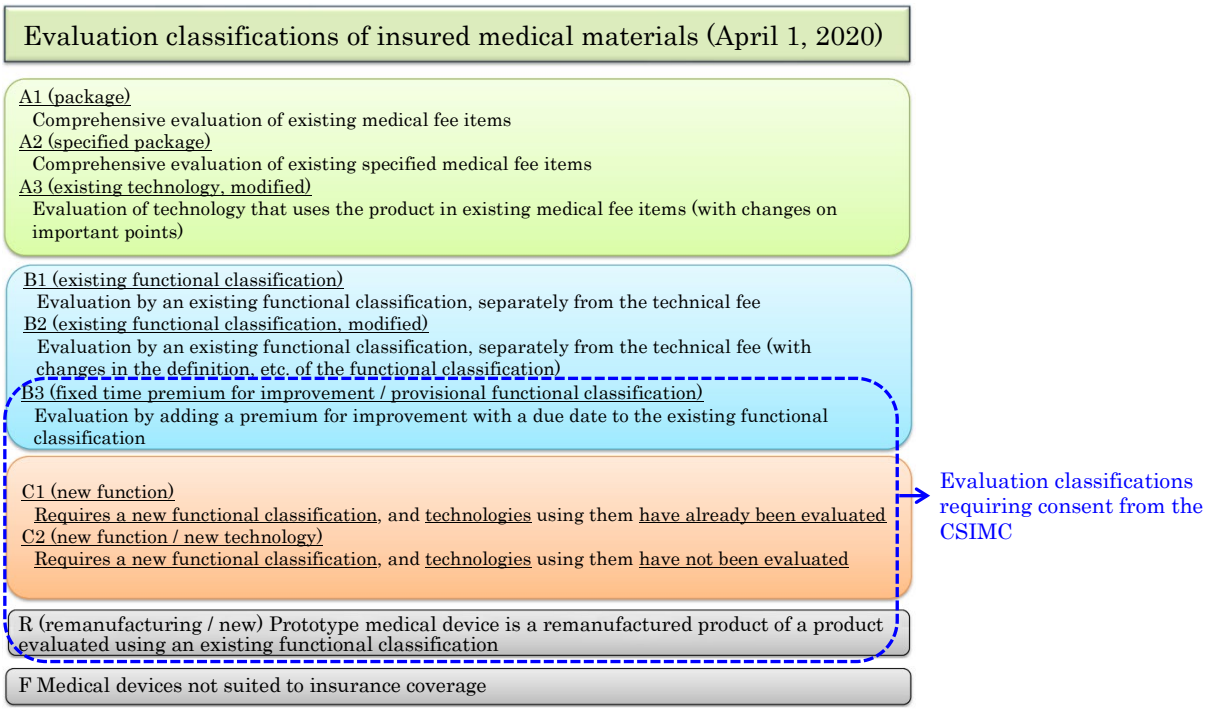

Figure 4: Evaluation Classifications of Insured Medical Materials

Health, Labour and Welfare, "Methods of Submitting Applications for Insurance Coverage related to Medical Devices", Published by the Economic Affairs Division of the Health Policy Bureau, 0207 No. 2 and Published by the Medical Economics Division of the Health Insurance Bureau, 0207 No. 2, February 7, 2020; Medical Devices Policy Office, Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare, Jimurenraku "Examples of Information Entry in Applications for Insurance Coverage related to Medical Devices", March 5, 2020; FY2016 Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare Outsourced Project "Guidebook on Insurance Coverage for Medical Devices", March 2017, etc.

[23] It can be difficult to verify final evaluation items for insured medical materials in the period leading up to insurance listing, as they may be implanted into the body for long periods of time or may be associated with highly innovative technology. The mechanism for products that require this type of evaluation based on actual use, which can re-evaluate the applicability of new functional classifications after insurance listing that takes actual use into consideration, for aspects which could not be evaluated when the product was introduced, is known as a "challenge application".

3.2.2. Evaluation method for DPC/PDPS (hospitalization)

For cases of DPC/PDPS, evaluation of medical devices based on the amount of work is only used for specified insured medical materials in classification B, used with items for surgery or anesthesia (Figure 5).

In addition, for remuneration evaluation in the DPC/PDPS system, calculation factors are set based on the input amount of medical resources, and do not reflect the effects (outcomes) of medical care services provided by medical institutions to patients, or the value of packaged medical devices, etc. However, if the average length of patient hospital stays is reduced by provided medical care services or by using valuable medical devices, under the DPC/PDPS system there is an incentive making it possible to calculate the remuneration for the length of hospitalization which has been set to a high point value.

2018 Revision of Medical Fees

Method of Calculating Medical Fees for DPC/PDPS (Items within the Scope of Packaging)

Items in the "Medical Fee Point List"		Comprehensive Evaluation	Evaluation based on Amount of Work
A. Hospitalization fees, etc.	Basic hospitalization fees	All	
	Premiums such as basic hospitalization fees	Premiums calculated for entire wards, etc. (Evaluation as functional evaluation factor I)	Premiums calculated for each patient, etc.
	Specific hospitalization fees	*Add difference from basic hospitalization fees	
B. Management, etc.		Preoperative medical management fees Postoperative medical management fees	Other than those at left
C. Home medical care			All (not subject to DPC packaging)
D. Tests		Other than those at right	Fees for cardiac catheter tests, endoscopic tests, diagnostic paracentesis and specimen collection (excluding blood collection)
E. Diagnostic imaging		Other than those at right	Premiums for diagnostic imaging management Arteriographic catheterization (major blood vessels)
F. Medication		All	
G. Injections		Other than those at right	Sterile formulation processing fees
H. Rehabilitation I. Specialized psychiatric treatment		Medication fees	Other than those at left
J. Treatment		Other than those at right (treatment set at less than 1000 points)	Treatment set at 1000 points or more Expenses related to artificial kidneys and peritoneal perfusion performed regularly for chronic renal failure
K. Surgery L. Anesthesia M. Radiation treatment			All
N. Pathological diagnosis		Other than those at right	Intraoperative rapid pathological specimen creation Pathological diagnosis and judgment fees
Medication fees		Other than those at right	HIV treatment medication Blood coagulation factor formulations (For hemophilia, etc.)

Figure 5. Method of Calculating Medical Fees for DPC/PDPS (Items within the Scope of Packaging)
Source: Materials from March 5, 2018 edition Summary of 2018 Revision of Medical Fees for DPC/PDPS, Medical Economics Division, Health Insurance Bureau, Ministry of Health, Labour and Welfare

3.2.3. Other comprehensive evaluation items in medical fees (outpatient)

There are items such as outpatient treatment fees, pediatric outpatient treatment fees, and community comprehensive treatment fees that also package certain tests, medical management for patients, etc. in addition to treatment practice by physicians. However, they are mainly evaluated based on the amount of work, and the technical fees for medical devices, etc. that are comprehensively evaluated are small.

3.2.4. Issues with the current Specified Medical Device System

As described above, the basic concept of the current medical device insurance reimbursement system was presented in the CSIMC Proposal in September 1993. It is clear that the main target of the system was the use of "tangible objects" due to the background of the time, and it shows a general concept for evaluation in individual insurance reimbursement directed toward the consumption and use of tangible objects.

In the area of pharmaceutical regulations, however, only tangible objects were regulated in the past, but the amended Pharmaceutical Affairs Act announced in 2013 states "Stand-alone programs used for diagnosis, etc. shall be subject to approval, certification, etc. for marketing as medical devices." Intangible objects consisting of programs were added to the Attached Table of the Government Ordinance for the Pharmaceutical and Medical Device Act which came into effect in 2014, and software became recognized as a medical device. As a result of this recognition of software as a medical device, the summarization of issues specific to its applicable fields was accelerated. Through activities such as the clarification of the scope of regulation targets, responses toward international cyber-security, and the 2019 revisions to the Pharmaceutical and Medical Device Act, relevant measures began to be conducted in sequence[24] which included the introduction of approval systems to appropriately respond to matters such as the characteristics of software which undergoes constant refinement and improvement, and technology such as AI whose performance is constantly improving.

As seen regarding pharmaceutical regulations, even if evaluation systems focusing on "tangible objects" are directly applied to the evaluation of "intangible objects", there are certain limits to the scope of discussions due to differences in the structures and backgrounds of those systems, and therefore there is a possibility that their spread may be impeded.

For example, the outcomes of medical technology delivered in an ideal medical care environment, such as one with highly-experienced physicians and an abundance of medical personnel, may not increase even with the addition of digital health.[25] However,

[24] For example: Counselor's Office Responsible for Medical Devices and Regenerative Medicine, etc. Products, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, "Announcement of Guidance related to New Drug Applications for Medical Device Programs", Jimurenraku, March 31, 2016; Chief, Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, "Partial Revision to 'Basic Concepts on Applicability of Programs to Medical Devices'", Published by the Compliance and Narcotics Division of the Pharmaceutical Safety and Environmental Health Bureau, 1228 No. 2, December 28, 2018; Chief, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, "Announcement of Next-generation Medical Device Evaluation Indicators: 'Evaluation Indicators related to Medical Diagnostic Imaging Support Systems using Artificial Intelligence Technology'", Published by the Medical Device Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau, 0523 No. 2, May 23, 2019; and Chief, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare and Chief, Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, "Basic Principles of Medical Device Cyber-Security according to the International Medical Device Regulators Forum (IMDRF), and Announcement of Guidance related to its Practical Application (Request for Communication)", Published by the Medical Device Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau, 0513 No. 1 and Published by the Pharmaceutical Safety Division of the Pharmaceutical Safety and Environmental Health Bureau, 0513 No. 1, May 13, 2020, etc.

[25] For example, endoscopic diagnostic imaging support software equipped with AI that can assist in distinguishing between tumors and non-tumors of colon lesions using approved ultra-magnified endoscopic images, and influenza testing software that is being developed to detect influenza follicles using AI and provide high-precision early diagnosis.

even if digital health does not lead to increased effectiveness, it may still have a significant positive impact on the overall medical care system by reducing the burdens on medical personnel, supplementing technological skills among them, and improving patient convenience. In particular, digital health is expected to contribute to improving the efficiency of medical care in an environment where a future shortage of medical personnel and measures to prevent infection will become matters of long-term importance.

On the other hand, under the current medical insurance framework, the "characteristics" of technology such as these are not actively evaluated as additional premiums. This is because under the current system, a major criterion for determining whether or not to perform an additional evaluation is whether or not there is an increase in effectiveness and safety for patients. In addition, since those evaluations are based on the amount of work for accumulated content in systems for providing people and goods, and in medical treatment and care, it is difficult under the current framework to evaluate the reduction of burdens on medical personnel, equalization of technology among medical personnel, and improvements to patient convenience.

Still, there are actually many examples of medical technology related to digital health that can contribute significantly to reducing the burdens on medical personnel, equalizing technology among medical personnel, and improving patient convenience, so failing to actively evaluate them will mean a loss of valuable opportunities to improve the efficiency of the Japanese medical care system. Therefore, in order for medical technology related to digital health to contribute to "extending the healthy lifespans of citizens" and "improving the productivity of medical care and nursing care services" in the future, a new evaluation system that has solved the issues of the current system is desired.

3.3. Evidence of medical technology related to digital health

According to Makoto Tamura, a researcher who made detailed studies on evidence of medical technology related to digital health across the world at PubMed[26], the prevailing opinion at the current time is that if payments are to be made from medical insurance just as for medical devices and pharmaceuticals, then similar evidence should be required for medical technology related to digital health.[27] With medical technology related to digital health, inclusion of subjects is possible at a relatively high speed, blind tests are possible, and there is no need to make exceptions for medical technology related to digital health.[28]

According to Mr. Tamura's research, compared to conventional technology, medical technology related to digital health makes it relatively easy to collect data on matters such as usage conditions of the technology, and there are many papers based on systematic reviews/meta-analysis. Most of these papers were evaluated based on Cochrane's risk-of-bias method. In the construction of evidence for medical devices, systematic reviews/meta-analysis papers considered that points which were not often seen in comparison were characteristics of evidence for digital health.

On the other hand, medical technology related to digital health, which is expected to give "the ability for medical personnel to provide diagnosis and treatment regardless of time or geographical constraints" or to "partially or completely replace or supplement diagnosis

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[26] Makoto Tamura: To What Degree Will Technology Change Everyday Medical Treatment? [Part 1] Digital Health Technology that will Change Medical Care, Beyond Health,https://project.nikkeibp.co.jp/behealth/atcl/column/00005/042500001/?P=1

[27] Greaves F, et al. What is an appropriate level of evidence for a digital health intervention? Lancet. 2019 Dec 22;392(10165):2665-7.

[28] Espie CA, et.al. Digital medicine needs to work. Lancet. 2018 Dec 22 2018;392(10165):2694.

and treatment processes by medical personnel", has a wide variety of places, times, and methods by which it can be provided, applicable target patients, medical care environments, conditions of involvement by medical personnel and patients, and methods for evaluating changes in patient conditions. Therefore, instead of evaluating the usefulness of the medical technology itself in the short term, it is considered to be more important to evaluate the final effects (outcomes) that can be expected from the technology over a longer term.

3.4. Basic viewpoint of medical technology evaluations with consideration for the "characteristics" of digital health

Because medical technology related to digital health has a fast life cycle and is frequently refined and improved, quick insurance coverage is required, and therefore it is believed that comprehensive evaluation is well suited to its "characteristics". However, in comprehensive evaluations the value of a medical device evaluated as part of technical fees becomes difficult to identify, so it will be necessary to evaluate the final effect of the applicable technology, or in other words to also proceed with outcome evaluation[29], so that the value of the medical device can be properly evaluated.

In other words, it is considered important to consider the concepts of value-based health care (VBHC) and health technology assessments (HTA) that take cost-effectiveness evaluation into account. Furthermore, among medical technology related to digital health, smartphone applications and other technology require active, timely, and appropriate involvement by medical personnel. For such technology which requires time for its effects (outcomes) to appear, in many cases the value of such technology, regarding the spread of the medical technology or improvements in patient conditions, is not clear at the time of marketing authorization (or approval) or insurance coverage, so it is presumed that re-evaluations will be conducted after a certain time has passed since data collection. By designing a system in which evaluation indicators and evaluation periods can be shared in

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[29] "Outcomes" include:
(1) "Health outcomes"Note) which improve a patient's health and prevent a disease from becoming more severe, and
(2) "Economic outcomes" which can reduce medical expenses (such as saving resources by reducing the burden on physicians and other medical personnel, or reducing unnecessary tests and medication) even if the "health outcomes" are equivalent.

Note) These include assessment components such as promotion of medical safety and improvement of diagnostic precision to obtain health outcomes.

Cases where the concept of outcome evaluation has been introduced in the current medical fee points:
For example, in order to prevent the introduction of dialysis at an earlier stage, there is a premium for guidance to patients with severe renal dysfunction, added to the management fee for guidance to prevent the introduction of diabetic dialysis, as an evaluation of improvement in a patient's condition by a decrease in serum creatinine, cystatin C, urinary protein excretion, eGFRCr, or eGFRCys.
In addition, for wards that intensively conduct rehabilitation which was introduced in the 2016 Revision of Medical Fees, there are fees for hospitalization in convalescent rehabilitation wards that require improvement in the ADL (activities of daily living) of discharged patients of a certain proportion compared to the time of their hospitalization (2016 Revision of Medical Fees). Also, evaluations related to bedsores in long-term care beds (incidence of bedsore occurrence) perform ongoing evaluations from the time of hospitalization using consistent indicators (DESIGN-R classification), with a premium for bedsore countermeasures (2018 Revision of Medical Fees) added to the basic hospitalization fee for long-term care beds which change the added points.

advance by relevant parties, it is believed that predictability for companies and insurers can be raised.

At the same time, if medical technology related to digital health, including AI technology, is expected to lead to benefits for patients such as rapid diagnosis, early treatment, or early discharge, the possibility of investigating expansions to the range of technical fees which package medical devices would be a development incentive for companies.

Viewpoints such as these are considered to also be methods for evaluating medical technology related to digital health in accordance with its “characteristics”.

4. Five recommendations on the evaluation of medical technology related to digital health

With regard to the state of insurance reimbursement of medical technology related to digital health which will be created in the future through technological innovation, the current medical fee system is an evaluation system based on the amount of work, which focuses on structure assessments as external criteria of systems for providing people and goods, and process assessments as evaluations of the content of implemented medical treatment and care. Under these conditions, evaluations which consider the "characteristics" of medical technology related to digital health cannot be conducted in the specified insured medical material system, which mainly sets prices individually for medical devices, and there is a possibility that evaluations may not be appropriate to the value of the applicable technology.

Based on the studies to date, we propose the following five suggestions on the state of evaluating medical technology related to digital health.

(1) Comprehensive evaluation
(2) Evaluation based on obtainable effects (outcomes)
(3) Data collection and re-evaluation of medical technology
(4) Establishment of a new organization to evaluate medical technology related to digital health
(5) Establishment of new remuneration items suited to medical technology related to digital health

The details are described below.

4.1. [Recommendation 1] Comprehensive evaluation

For medical technology related to digital health (items among them that are considered medical devices), carry out "comprehensive evaluations" as part of technical fees.

This will arrange an environment in which even medical devices, which have short life cycles and frequent refinements and improvements, can be introduced into insurance quickly after marketing authorization (or approval) is obtained under the Pharmaceutical and Medical Device Act since they are packaged in technical fees. As a result, companies will be relatively free to negotiate prices with medical institutions since medical devices are packaged in technical fees and individual prices are not set for them.

4.2. [Recommendation 2] Evaluation based on obtainable effects (outcomes)

The point system currently used for drug pricing and evaluation of specified insured medical materials[30] is an evaluation method for "goods". For medical technology related to digital health, there is a need for a method that can evaluate effects (outcomes) by accurately evaluating their value, instead of using quantitative criteria for direct evaluation as "goods".

With regard to insurance reimbursement of medical technology related to digital health, the evaluation system based on the amount of work, which focuses on structure assessments and process assessments, will be revised to become a mechanism that also evaluates the effects (outcomes, both health outcomes and economic outcomes) brought about by the applicable technology.

When doing so, evaluations will also be actively performed on the effects for reducing medical expenses which are obtained through improvements in the quality of medical care, significant savings of medical resources, and shortened times for service provision, brought about by medical technology related to digital health.

4.3. [Recommendation 3] Data collection and re-evaluation of medical technology

Medical technology related to digital health is believed to have higher compatibility with the collection of data on outcomes than conventional medical technology. It also makes it possible to collect objective data by coordinating with PHR (personal health records), ePRO (electronic patient-reported outcomes), etc., and from the viewpoint of value-based health care, it can be used mainly for the evaluation of health outcomes obtained by patients. In addition, reduced burdens on medical personnel and shortened treatment times, which are significant benefits of medical technology related to digital health, are also viewed as important indicators for evaluation.

Mechanisms will be introduced for re-evaluation (premiums and subtractions are also possible) as medical technology after a certain time has passed since data collection.

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[30] In discussions by the Central Social Insurance Medical Council (CSIMC), quantitative evaluations have been requested for new insurance coverage of specified insured medical materials. Therefore, based on opinions from the CSIMC Insured Medical Materials Expert Group, a research team was organized by the Health, Labour and Welfare Science Research Project which studied quantitative methods of price determination, and the points (trial proposal) based on the report from this research team on the quantification of premiums are used as a reference when adding actual premiums. This consists of research on a quantitative calculation method of correction factors for average profit ratios and research on quantitative evaluation in criteria for insurance reimbursement price calculation of specified insured medical materials, in the Health, Labour and Welfare Science Research Grant (Health, Labour and Welfare Special Science Research Project) Criteria for Drug Pricing (Cost Calculation Method) (Principal Researcher: Tomoaki Imamura). The results are described in detail in "Research Project on Quantitative Methods related to Price Determination of Pharmaceuticals and Specified Insured Medical Materials (Medical Devices)", Journal of Health and Welfare Statistics Vol. 62 No. 15, December 2015.

4.4. [Recommendation 4] Establishment of a new organization to evaluate medical technology related to digital health

With many new companies expected to enter the market in the future, the evaluation system for medical technology related to digital health must be highly transparent and predictable for companies. Specifically, medical technology related to digital health requires not only knowledge related to conventional medical devices and their evaluation, but also specialization in fields which differ from previous evaluations of medical technology (health data science, algorithm design and analysis, big data analysis, behavioral economics, etc.), and experts in these fields must have the perspective of performing evaluations together with medical personnel. In addition, in anticipation of evaluations on the effects (outcomes) that can be obtained in the future instead of evaluations based on the amount of work, it will be necessary to carry out specialized studies from the viewpoints of collected data items that match the characteristics of medical technology related to digital health, and their evaluation.

Therefore, even for studies on technical fees related to physicians and other medical personnel, it will be necessary to establish a new specialized organization in CSIMC to conduct expert studies reflecting specialization and industry opinions, just as for pharmaceuticals and medical devices, which are separate from the regular discussions held at CSIMC General Meetings and meetings of the Subcommittee on Basic Issues with Medical Fees.

4.5. [Recommendation 5] Establishment of new remuneration items suited to medical technology related to digital health

Concurrently with [Recommendation 4], it is also necessary to establish new items in the point list to clearly indicate that medical technology related to digital health is being evaluated with consideration for the positioning of evaluations on remuneration.

Possible methods for the creation of these new items include the addition of evaluations as suffix numbers of similar existing technical fees in the same way as for surgical procedure fees, or the addition of "parts" of special treatment fees themselves (same handling as medical management, etc., home medical care, treatment, surgery, etc.) as completely separate evaluation items.

Indication as completely separate evaluation items will make it possible to clearly distinguish between medical technology related to digital health which is and is not evaluated by medical insurance.

*Reference

Even for surgical procedure fees, clearly indicating that new technology is evaluated has created a clear distinction between those evaluated by medical insurance and those that are not. For example,

K843	Prostate cancer surgery	41,080 points
K843-2	Laparoscopic prostate cancer surgery	77,430 points
K843-4	Laparoscopic prostate cancer surgery (using endoscopic surgical support equipment)	95,280 points

* As indicated here, when laparoscopic or endoscopic surgical support equipment is used, there is a clear distinction between technology that is and is not evaluated by medical insurance.
* In principle, items without these suffix numbers are not subject to insurance coverage even if laparoscopic or endoscopic surgical support equipment is used.

5. Issues that require further future study regarding medical technology related to digital health

In the previous chapter, five recommendations were presented on the state of insurance reimbursement of medical technology related to digital health. It is anticipated that in the future, industry-academia-government discussions will be held on the state of insurance reimbursement based on those recommendations, which will more deeply examine methods of evaluating medical technology related to digital health. This study group has examined matters regarding medical technology related to digital health which require further examination, and has indicated specific examples.

When doing so, a future-oriented viewpoint was taken and medical technology which could possibly appear very soon was envisioned. It was considered that discussions should be started from the current time on that technology, and was assumed that it would be properly evaluated from the most recent Revision of Medical Fees, separated into major classifications with risks and outcomes treated as the focal points of evaluation. The following three issues were then discussed.

Note that the names of the classifications were set by this study group. In the following sections, the issues that should be discussed in the future regarding the state of insurance reimbursement are indicated for each of these classifications (Figure 6).

(1) Digital diagnostic support technology
(2) Digital medical treatment support technology
(3) Revolutionary technological innovations

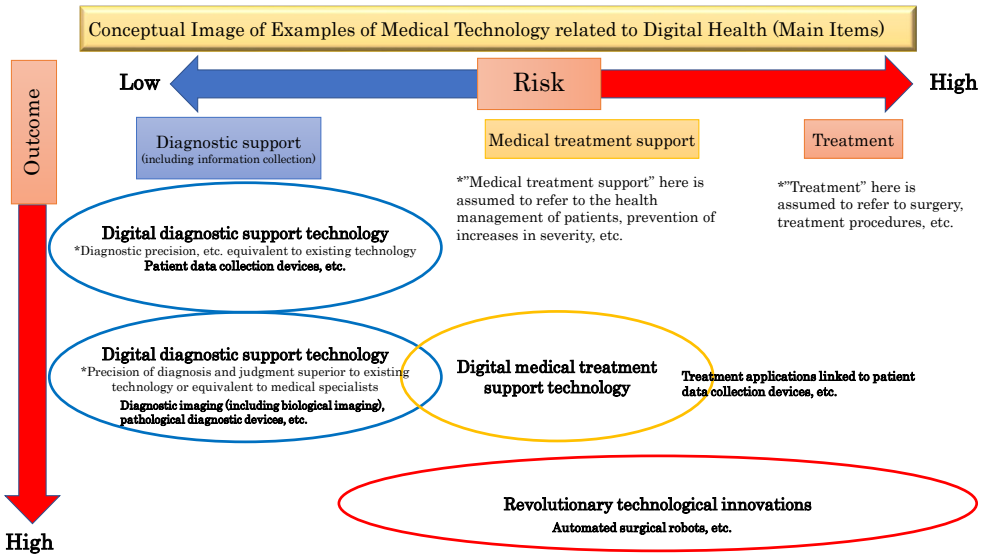

Figure 6: Major Examples of Medical Technology related to Digital Health

5.1. Studies on digital diagnostic support technology

There are some medical devices (such as software) that support diagnosis and judgments made by physicians and have no patient intervention themselves, but only transfer patient information to medical institutions, and also medical technology (medical devices) that has already been put into practical use at medical workplaces, in fields such as diagnostic imaging and pathological diagnosis.

In addition, some of these digital diagnostic support technologies are medical technology (medical devices) not required to be evaluated as insured medical materials, at the discretion of companies.

Examples of digital diagnostic support technology vary widely in function and performance, from those with diagnostic precision equivalent to existing technology, to those which can provide effects (outcomes) to patients equal to or greater than diagnosis by a medical specialist. Therefore, the study was divided into two major categories.

Current related items

- Items with diagnostic precision, etc. equivalent to existing technology

  e.g. Circulatory dynamics analysis programs[31], medical devices used for remote monitoring premiums[32], etc.

- Items for which the effects obtainable by patients are equivalent to or greater than those from diagnosis from medical specialists

  e.g. Various types of CAD (diagnostic imaging auxiliary devices), pathological diagnostic devices, and software to discover lesions and perform pathological diagnosis using AI such as biological imaging

5.1.1. Items with diagnostic precision, etc. equivalent to existing technology

If the precision of diagnosis and judgment is unchanged from that of existing technology even with the use of digital diagnostic support technology, it is possible to respond even with current evaluation methods, such as by:

- Considering setting points as an alternative to existing technology, as with circulatory dynamic analysis, or
- Evaluating some of the management fees lost due to the extension of consultation intervals, as with remote monitoring premiums.

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[31] Circulatory dynamic analysis program, Item name "Heartflow FFR_{CT}", Approval Number 22800BZX00418000; A program to assist in the diagnosis of patients with stable clinical conditions suspected of having coronary artery disease, by performing computational fluid dynamics analysis based on coronary artery computed tomography data (cardiac CT) to calculate FFR_{CT} (Fractional Flow Reserve) values. An indicator known as FFR is used for the evaluation of functional ischemia, but since the FFR technique is invasive and requires complicated operation, this program provides a non-invasive indicator that can assist in the evaluation of ischemia.

[32] Calculated when patient information is monitored remotely using devices equipped with information transmission functions, after which instruction and management necessary for medical treatment are provided. They can include cardiac pacemaker instruction management fees, oxygen therapy instruction fees for at-home patients, and continuous positive airway pressure therapy for at-home patients.

5.1.2. Items for which the effects obtainable by patients are equivalent to or greater than those from diagnosis from medical specialists

Some examples of medical technology (medical devices) with diagnostic and judgment precision equivalent to or higher than that of medical specialists have already been put on the market, but due to the lack of predictability in the evaluation of medical fees and in light of the approval content in the Pharmaceutical and Medical Device Act (since the approval content basically states that they are a supplement to diagnosis made by physicians in relation to Article 17 of the Medical Practitioners Act), in reality they are used at actual medical workplaces while being packaged in the technical fees of existing medical fees, without being evaluated as individual technologies. In such cases, the company who developed the technology can negotiate with medical institutions to determine the sales price in order to recover the development expenses, but since there are no evaluations on remuneration aside from the existing technical fees for the medical institution using the technology, it will simply result in a structure where there is an increase in the purchase expense.

In order to change this situation to create an environment in which medical institutions can widely introduce valuable digital diagnostic support technology and increase the predictability of medical fees for development companies, it will be necessary to establish a new method for the evaluation of digital diagnostic support technology which is appropriate as an "evaluation method for digital diagnosis support technology", regardless of whether considering to set points in comparison with existing medical fee items, or to evaluate the value of the technology itself and then set points.

- Examples of medical technology (medical devices) whose precision of diagnosis and judgment is equivalent to or higher than that of medical specialists
  - Medical technology (medical devices) for diagnostic imaging and pathological diagnosis, etc.
  - When implementing medical technology related to biological tests (endoscopy, etc.), diagnostic software that can point out the locations of lesions in real-time, diagnostic software that can diagnose diseases from biological images using AI, diagnostic software that uses new digital biomarkers, etc.

  are conceivable.

For medical technology related to diagnostic imaging and pathological diagnosis, effects (outcomes) consisting of the reduction of unnecessary tests up until diagnosis, and a decrease in overlooked conditions, can be obtained by providing "accurate diagnosis" to patients. For medical technology related to biological tests (endoscopy and tests using various types of medical scopes), these effects (outcomes) can be obtained by pointing out the locations of lesions when the tests are implemented, with precision equivalent to or greater than that of medical specialists, and then providing judgment and diagnosis on the disease conditions.

In addition, the use of applicable technology for either case of medical technology indicated above will have the effect (outcome) of reducing burdens on physicians at the time of diagnosis.

Based on the above, regarding evaluation methods of digital diagnostic support technology for which the effects obtainable by patients are equivalent to or greater than diagnosis by medical specialists, evaluations consisting of:

- If there is a technical fee which has already been set (premium for diagnostic imaging management, premium for pathological diagnosis management, colonoscopy testing, etc.), add a further premium to the applicable technical fee based on the effects (outcomes) obtainable by the medical technology related to digital health,

or

- From the viewpoint that the use of medical technology related to digital health can ensure "accurate diagnosis" equivalent to the situation where a medical specialist is present, even at medical institutions where there are no medical specialists, review facility criteria such as the requirements for the assignment of medical specialists, and alleviate those criteria by introducing (using) the applicable medical technology (medical devices),

are considered possible.

In order to increase predictability for companies when adding premiums to technical fees, and since the effects (outcomes) that can be obtained for each type of medical technology after calculation formulas which are easier to understand even for insurers who provide payments have been systematically introduced will differ for each case, it is important to set evaluation indicators for each technology, and to design a system in which the extent of effects and the approximate amount of premiums can be easily understood.

When doing so, the premiums added to technical fees are assumed to be based on system design focusing on economic outcomes (efficiency, etc.). However, it is also necessary to determine the true value of the technology by collecting and re-evaluating data on the true effects that can be obtained by patients and the obtainable health outcomes (improvement of prognosis, etc.), separately from the early introduction of medical technology related to digital health and the encouragement of corporate motivation for development. Therefore, it is appropriate to consider premiums which use economic outcomes as temporary measures to be carried out during the data collection period until re-evaluation.

It is likely that it will be necessary to discuss the setting of evaluation indicators such as these even in the "new organization" which evaluates medical technology related to digital health.

○ Examples of evaluation indicators for economic outcomes
- ➢ Reduction of wastefulness, made possible by accurate diagnosis (including matters from the perspective of medical safety)
  - ・ Decrease in number of consultation visits
  - ・ Reduction of duplicate tests, treatment procedures, etc.
- ➢ Reduction of burdens on medical personnel
  - ・ Reduction of diagnosis time
- ➢ Shorter hospitalization periods by replacing procedures with non-invasive procedures

In addition, in studies (reviews) of facility criteria for the case of medical technology with obtainable effects (outcomes) equivalent to or greater than those from medical specialists, it will be necessary to summarize the relationships with physicians other than medical specialists (or medical institutions without medical specialists).

It must be noted that the evaluation of remuneration only for (the value of) medical technology (medical devices) will not lead to the evaluation of medical specialists themselves, and just the introduction of medical technology (medical devices) may result in an increase in the income of physicians other than medical specialists (or medical institutions without medical specialists).

On the other hand, it is important that such digital diagnostic support technology be appropriately evaluated and widely used in order to correct for the uneven regional distribution of medical specialists and to reduce the burden on physicians. Therefore, it will be necessary to coordinate with studies on a medical care provision system (whether it will be subject to re-evaluation in terms of actual results such as for the “5 illnesses, 5 fields”, and the concepts of regional medical care) when setting facility criteria to be evaluated.

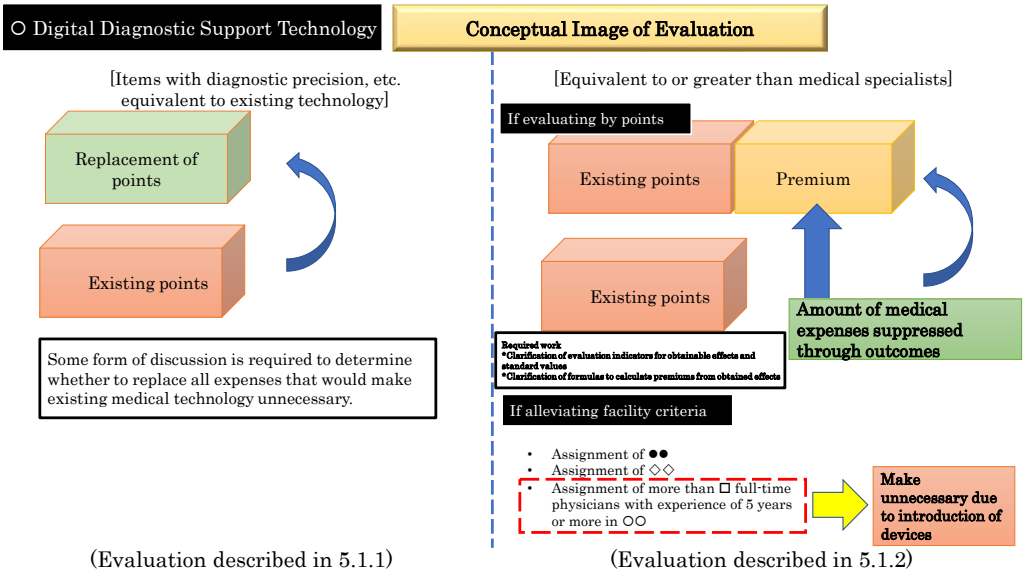

Figure 7: Conceptual Image of Evaluation of Digital Diagnostic Support Technology

5.2. Studies on digital medical treatment support technology

These are items which can serve as a substitute for treatment of patients by physicians (here, this refers to guidance, management, and prevention of increases in severity for patients), and where the medical technology itself has functions for intervention with the patient.

- Intervention using smartphone apps fall into this category.

  e.g. Nicotine addiction treatment apps, treatment intervention apps to encourage behavioral changes for diabetic patients, etc.

Evidence from digital health indicates that the appropriate involvement of medical personnel, rather than intervention only by medical devices, is an important factor in intervention using digital medical treatment support technology for patients, particularly those with chronic diseases.

Based on such evidence, the existing evaluation system based on the amount of work was reviewed as an evaluation of the case where treatment is provided using digital medical treatment support technology primarily for patients with chronic diseases, and outcome evaluations focusing on the effects (outcomes) obtainable by patients (cohorts) were examined as a new mechanism capable of appropriately evaluating the value of medical technology related to digital health.

5.2.1. Concept of new mechanism (outcome evaluation)

A new mechanism will be studied in which medical institutions provide patients (cohorts) with services for a certain period of time, collect and evaluate patient health outcome information obtained during that period, and then carry out payment to the medical institutions who provided the applicable services, according to the status of health outcome acquisition by patients (cohorts) (Figure 8).

The basic idea of the new mechanism is not to evaluate the digital medical treatment support technology itself, or the facts and actual results of using the medical technology (so-called output) as in past evaluations based on the amount of work. Instead, it is meant to evaluate whether the provided services have led to health outcomes for patients (cohorts) as a result, with the evaluation (remuneration) of the digital medical treatment support technology itself packaged in the technical fees provided from medical institutions to patients. Even if services were provided, future evaluations cannot be obtained unless the health outcomes of the patients (cohorts) have been achieved.

In addition, the provision of medical care services and services to prevent increases in severity to patients (cohorts) should not be limited to one medical institution, but should incorporate the concept of community-based comprehensive care, and should make it possible to designate a group of medical institutions suitable to the situation (national insurance, employee insurance, etc.) of the patients (cohorts). When this is done, the combined utilization of digital medical treatment support technology, remote medicine (online medical treatment), remote patient data collection devices, and related technology should be actively promoted so as to lead to health outcomes for the patients (cohorts).

In order to obtain health outcomes for patients (cohorts), extend healthy lifespans, and promote health, it is important to intervene from the time before the onset of illness. Therefore, it will be necessary to build a consensus among relevant parties and arrange systems so that medical institutions (groups) in coordination with local governments can implement services for the "prevention" of diseases (medical checkups, health guidance, nutritional guidance and exercise instruction to promote health, etc.) that are not currently within the scope of medical benefits (in other words, insurance coverage).

On the other hand, by strengthening the functions of insurers (regardless of national insurance or employee insurance) and managing the data (personal health records, receipt data, medical record data, etc.) of insured persons (patients (cohorts)), it will be possible to make progress checks to determine whether interventions with patients (cohorts) are proceeding successfully, and to provide recommendations to medical institutions (groups). As described in the previous chapter, medical technology related to digital health has a high compatibility with data collection, so it is expected to also be utilized for such efforts to strengthen the functions of insurers.

At that time, the items which should be verified are considered to be the following.

○ Examples of verification items

- Applicable diseases
  - Whether or not the digital medical treatment support technology to be developed is well suited to the indicated diseases, etc.
- Age, gender, and group affiliation of patients as cohorts
  - "Cream skimming": settings to prevent selection of certain patients, etc.
- Methods of involvement by medical institutions
  - Whether participation is individually or as a group
  - Advisability of participation, extent of freedom, etc.
- Methods for evaluating health outcomes
  - Who will set the reference points and how they will be set
  - Methods for data evaluation
  - Data collection (evaluation) periods
  - Human resources and costs required to perform evaluation, etc.
- Compensation paid to medical institutions (groups)
  - Fiscal sources of remuneration for medical institutions that have obtained outcomes, methods for calculating compensation, etc.
- Measures in the event of failure to produce results
  - Responsibilities of medical institutions (groups) or patients (cohorts), compensation, etc., if outcomes could not be obtained after a certain amount of time has elapsed

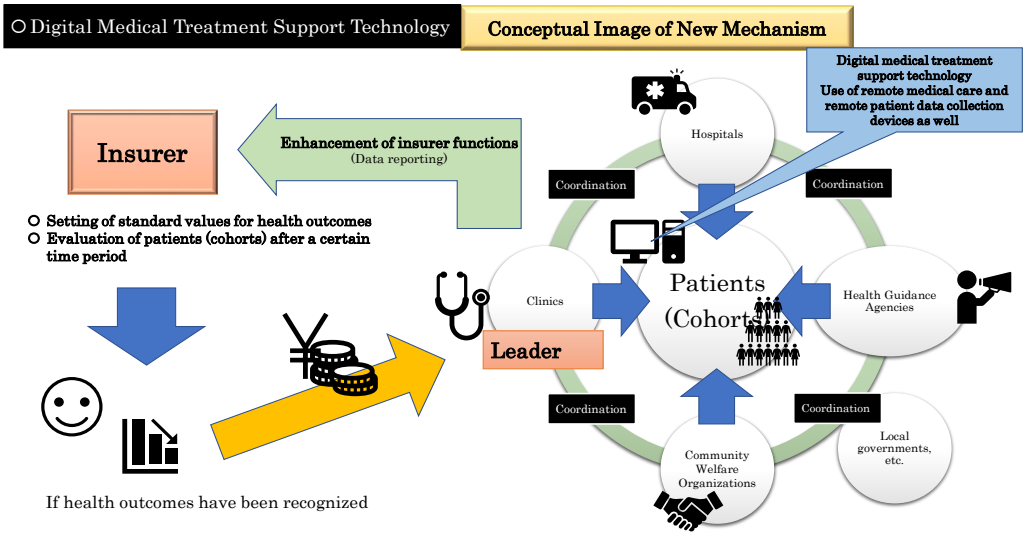

Figure 8: Conceptual Image of Evaluation of Digital Medical Treatment Support Technology (Conceptual Image of New Mechanism)

At the time of introduction of the DPC/PDPS system and the cost-effectiveness assessment system, the circumstances for their introduction were conducted carefully and thoroughly, including certain trials and verification which were carried out first, so when studying the new mechanism equivalent processes must be followed. However, the study group has decided to present the points that should be verified, in order to advance future studies by identifying the issues that are necessary for the introduction of such a system.

On the other hand, even under these conditions there is a possibility that new digital medical treatment support technology will be subject to insurance coverage. Therefore, in evaluations for the time being it will be necessary to take measures such as adding premiums which have converted the effects of such medical technology into numerical form, after comparison with existing similar medical fee items. Meanwhile, it is also considered important to require data collection on health outcomes, which are the true effects (outcomes) that can be obtained by patients (Figure 9).

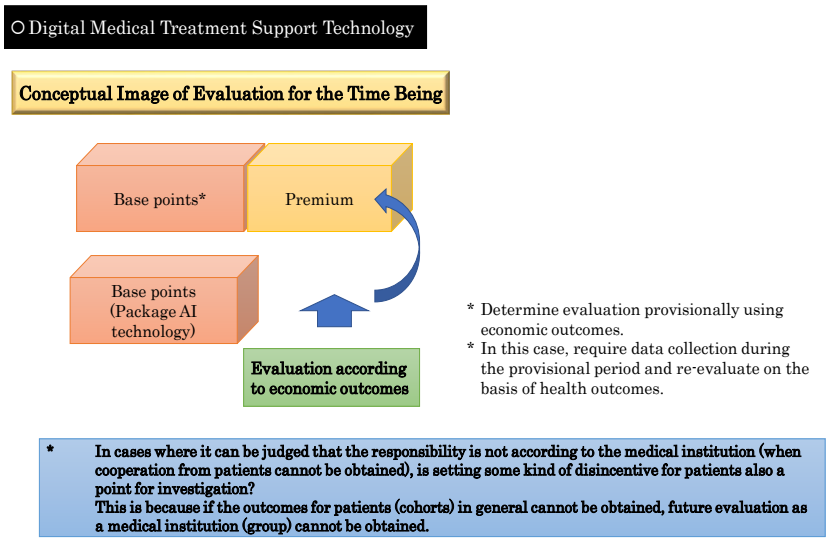

Figure 9: Conceptual Image of Evaluation of Digital Medical Treatment Support Technology for the Time Being

5.3. Studies of revolutionary technological innovations

It cannot be predicted when revolutionary technological innovations that cannot be evaluated based on existing premises for evaluation of remuneration (provisions of the Medical Practitioners Act, Medical Service Act, Pharmaceutical and Medical Device Act, Health Insurance Act, etc.) will come into the world. In such a rapidly changing world as our own, it may even be tomorrow.

Therefore, it will be too late to start examining evaluation methods for such revolutionary technological innovations at the time of their emergence. In order for development companies to assume a leading role in the world, it is believed necessary to carry out studies at the current time and as soon as possible in preparation for the time when such technology becomes available to the world. Therefore, the issues that should be discussed are indicated below.

Conceivable issues include:

- Can the technology be used only at the discretion of the patient, without intervention by a physician?

  e.g. Diagnosis by automatic diagnostic software, etc. on the Internet, using smartphone images or other such resources

- Can the technology be used freely in locations other than medical institutions?

  e.g. Treatment performed using medical technology at home or other such locations (devices: automated surgical robots, etc.)

- What are the conditions and locations of responsibility in the event that a medical problem should occur?

  e.g. Self-responsibility or corporate product liability, c.f. autonomous driving technology for automobiles

- Is it acceptable for companies to set compensation at that time, at their own discretion?

  e.g. Whether to pay as medical insurance, and if so, what is the system design and will medical treatment be at one's own expense

Each of these issues must be put into order.

[Concept under assumption of evaluation by medical fees, etc.]

In an environment where revolutionary technological innovations exist enabling patients to use them without depending on the guidance of physicians or in places outside of medical institutions, the assumptions for payment of medical fees will differ from the current ones, and in principle, there should be freedom of medical care entrusted to the market with prices set freely by companies. However, with the goal of allowing citizens to widely enjoy the benefits of such technological innovations and increasing the predictability of incentives for corporate development investment, if they are assumed to be evaluated as medical fees, it is considered to be one option to apply wider shared billing schemes which partially place the burden on patients, instead of treating the entirety of medical technology as subject to insurance coverage[33] (Figure 10).

[33] Wider shared billing schemes are divided into two categories: treatment under evaluation, which is based on the assumption of future insurance coverage adoption (advanced medical care, patient-requested treatment), and selective treatment, which is not based on that assumption.

At that time, limiting the period of wider shared billing, such as requiring the collection of data on the effects (outcomes) for a certain period of time, while also measuring the effects on patients, will make it possible to determine whether they will be subject to health insurance coverage in the future or will be considered treatment at one's own expense.

More specifically, it will be possible to set technical fees for the portion equivalent to revolutionary technological innovations, and after designating them as wider shared billing schemes, the portion of profits added as an incentive for corporate development can be set as co-payment by patients.

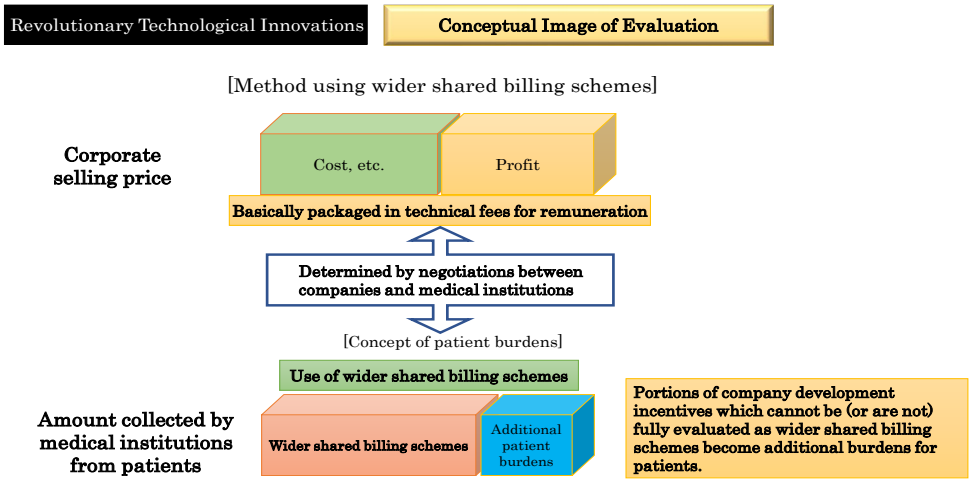

Figure 10: Conceptual Image of Evaluation of Revolutionary Technological Innovations

6. Conclusion

This research project aims to provide innovative medical technology from Japan to citizens and patients ahead of the rest of the world, amid intensifying global competition in the development of digital health including AI. It offers proposals regarding the future state of insurance reimbursement of medical technology in anticipation of advances in digital health, in order to raise the predictability of insurance reimbursement, which is an exit theory for development investment required by many participating companies, and to encourage further motivation by companies toward research and development.

It is a response to the fact that there have still been no discussions held on insurance reimbursement of medical technology related to digital health, which is considered to be the most important issue for companies when engaging in commercialization, even as the promotion of research and development and the arrangement of environments related to digital health in Japan are proceeding, and the handling of laws such as the Medical Practitioners Act and the Pharmaceutical and Medical Device Act is being clarified.

With consideration for the characteristics of digital health, this study group has concluded over five study sessions that insurance reimbursement of medical technology related to digital health must include mechanisms to evaluate the outcomes brought about by the applicable technology in comprehensive evaluations.

This proposal differs in concept from the current evaluation system based on the amount of work, which focuses on structure assessments as external criteria of systems for providing people and goods, and process assessments as evaluations of the content of implemented medical treatment and care.

In addition, medical technology related to digital health is well suited to outcome assessments due to its high compatibility with the collection of outcome data. This makes it possible to actively evaluate improvements in the quality of medical care resulting from medical technology related to digital health, and effects for the reduction of medical care expenses achieved through significant savings of medical resources and shortened times for service provision, as well as to perform re-evaluations after a certain period of time has passed.

For this reason, in addition to the knowledge gained in the past through the evaluation of medical devices and technology, medical technology related to digital health inevitably requires specialization and specialists from other different fields, so it will be necessary to establish a new specialized organization in the CSIMC. It will also likely be necessary to create new remuneration items based on medical technology related to digital health, in order to clearly distinguish between medical technology related to digital health which is and is not evaluated by medical insurance.

This proposal report summarizes these matters as five recommendations on the state of evaluation of medical technology related to digital health.

Furthermore, studies were carried out on issues to be discussed from here on as examples of medical technology related to future digital health, examined from the three categories of <1> digital diagnostic support technology, <2> digital medical treatment support technology, and <3> revolutionary technological innovations.

So-called “outcome evaluations” are not limited to medical technology related to digital health, but are expected to be introduced in the future for insurance reimbursement of regenerative medicine products, genetic testing, treatment, and other matters, and will have an important place in the re-evaluation of existing medical technology.

However, as shown by plans such as the FY2020 Action Plan for Innovative Business Activities (Ensuring Effective and Efficient Medical Care and Welfare Services through the Application of Technological Innovation)[34] and the Intensive Reform Plan for Data Health to Respond to the "New Normal" (Process of Data Health Intensive Reform Plan (2 Years))[35], initiatives by the government with the theme of "medical + digital" are in progress, and it is believed that the results of this study and their quick achievement will contribute to "extending the healthy lifespans of citizens" and "improving the productivity of medical care and nursing care services".

We hope that the results of this study will serve as a foundation for studies by other related parties, and that it will promote further discussions so that a system can be formed and established.

[34] Headquarters for Japan's Economic Revitalization, "FY2020 Action Plan for Innovative Business Activities" (July 17, 2020)
[35] Headquarters for the Promotion of Data Health Reform, Ministry of Health, Labour and Welfare, "Intensive Reform Plan for Data Health to Respond to the 'New Normal'" (July 30, 2020)