Draft EBC for Public-Private Sector Dialogue in 2022

November 28, 2022

European Business Council (EBC)
Medical Device and IVD Committee
Medical Fee Subcommittee / Pharmaceutical Affairs Subcommittee

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1. Stable supply - Response in normal times and emergencies

Proposal for Public-Private Sector Dialogue in 2022

Current situation ; Securing the emergency medical supply system in response to the pandemic (COVID-19)

- Stable supply of medical device continued to be required in the situation of the spread of corona infection and in a situation where medical institutions were under pressure.
- The company faced a reduction in air cargo flights, and production was unstable due to unstable material shortages.
- In addition, it was difficult to secure airmail, and transportation costs increased significantly. Sales of normal business continued to be difficult
- Stable supply was required, but efforts to maintain a large inventory led to a sharp rise in maintenance and management costs.
- As a result, there were concerns about the company's continued existence.

Issue ;

As a countermeasure, following the financial support for securing beds in medical institutions during normal times,

- ➢Explore the possibility of financial support for inventory management
- ➢In the event of an emergency, consider a system in which the national government sets air cargo quotas for medical use on regular flights.

2. Medical DX - Expansion to support system of telemedicine and medical monitoring

1. Current Status - Telemedicine Support System

- Online medical consultations, which were delayed compared to overseas, have been expanded as an emergency response to COVID-19, improving convenience for patients. Further expansion is expected. In particular, **the diagnosis and treatment of Doctor to Doctor by remote control** overseas is globalizing and spreading. On the other hand, in Japan, diagnosis is only a tool for instruction of operation by remote communication. Ex.: Only ordering from the doctor at the outside facility to the operating technician at the facility where the device is installed

- Utilization of these technologies is consistent with improving the quality of medical care, ensuring its accessibility, and maximizing therapeutic effects through active involvement with patients who need treatment. In the social issues such as population decline and a decrease in the number of surgeons, telesurgery will contribute to the standardization of high-quality medical care, and in addition, it will contribute to public welfare by improving medical standards. It is also expected to have the effect of promoting technological development in related fields in Japan.

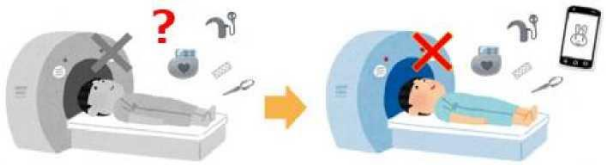
- Therefore, it will greatly contribute to the shortage of doctors in Japan and the standardization of medical care.

2. Current Status - eHealth and Related

- Although digital health (eHealth) is not progressing as compared to Europe, its development is expected, and in Japan, the expansion of PHR to medical care has been stipulated as a basic policy (HONEBUTO) medical DX. Related to this is the utilization and sharing of patient information. In particular, sharing information for patients with implanted medical devices can be a challenge.

Request ; Further promotion of telemedicine and digital health

- Although deregulation is progressing toward the realization of telemedicine, we ask that you continue to discuss deregulation, etc., toward concrete realization in clinical settings.
  (Ex.: D-D operation/manipulation support system of remote treatment, D-D imaging support system of remote diagnostics etc.)
- In order to realize eHealth, we would like to set up a forum for joint consultations between the public and private sectors so that concrete actions can be taken.
- Integration of implantable medical device information into systems: It is expected that information such as the patient notebook will be incorporated into my number card.



MRI examinations of patients with implanted devices such as cochlear implants, cerebral aneurysm clips, and coronary artery stent are sometimes performed without specifying the material or manufacturer, as the patient's declaration of examination is ambiguous.

Medical DX Integrating Information on Implanted Medical Devices to My Number Cards

System to confirm the information of implanted devices at medical institutions nationwide

A system to confirm the information of implantable medical devices at medical institutions nationwide in order to avoid accidents at the time of emergency or MRI imaging, or when changing hospitals Please expand the scope of information subject to My Number card registration to include information on implantable devices

Implantable device information | Patient notebook | Patient record book **MRI** card

System to allow viewing of own implantable device information

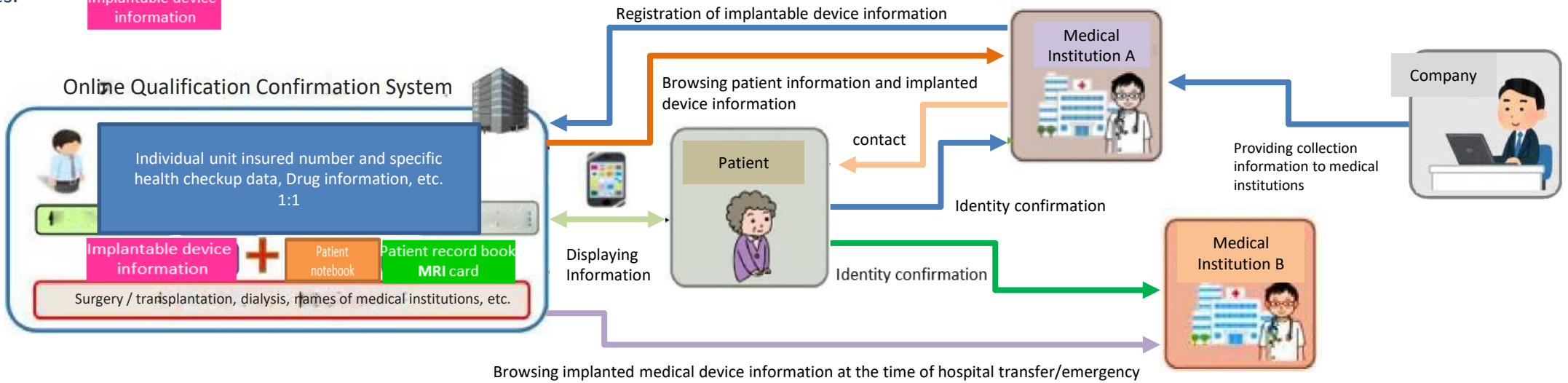
Access by citizens and patients to their own information on implanted devices via PCs, smartphones, etc. ・ A system that enables use

Patient notebook | Patient record book **MRI** card

Digital Tracking of Designated Medical Devices

When medical devices are collected, the medical institution inquires about the implantable device information from the lot number (information included in UDI) published by the company to the operator, and the operator responds to the patient information online. From the viewpoint of privacy protection, it is possible to limit the database of patient information in companies.

Implantable device information



3. Evaluation of medical device (medical technology) innovation
- Consideration of a provisional license system (provisional approval and provisional insurance system) for SaMD / SiMD

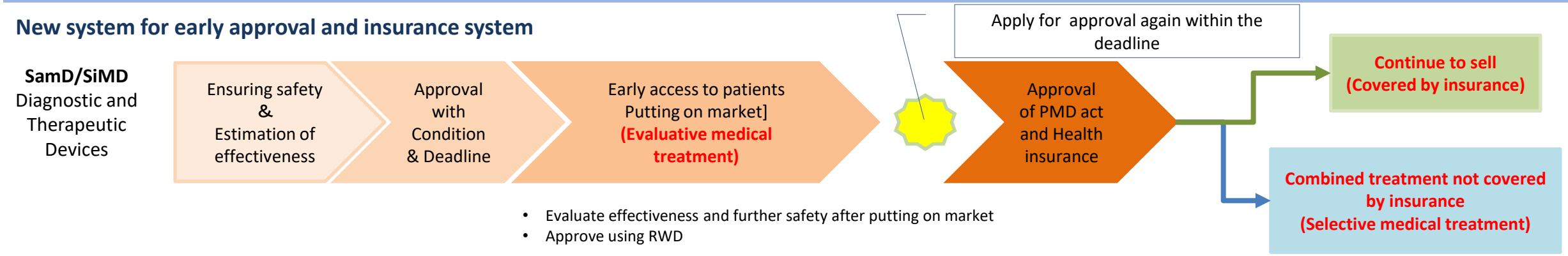
[Current status]

- In the case of Programmed Medical Devices SaMD or SiMD (Software) in Medical Device etc., the development rotation is fast and it takes time to obtain Evidence for insurance coverage, and there are cases where the value of the product is lost. Alternatively, there are cases where the development or putting on the market is abandoned due to lack of predictability by caused many major changes. In order to revitalize development, it is necessary to recover development costs as soon as possible.
- In the revision of the act in Heisei 25, a chapter on regenerative medicine products was established and approval system with conditions and deadline for regenerative medicine products was introduced.
  In Heisei 27, regenerative products were approved under this conditional and time-limited approval system, and real example pf approval system was implemented to confirm effectiveness and further safety after putting on market.
- In the Heisei 29, a notice of rebalancing was issued, and early approval has begun to take place.
- In addition, in recent years, a system of having a provisional license system with insurance for programmed medical device has started oversea, and a certain degree of predictability is secured in the development and sales of start-up companies. (Germany ; DiGA System)

Issue ;

In order to ensure early access to patients, the public and private sectors will consider a system in which products whose safety is ensured by QMS standard, etc. are first put on market, and then re-evaluated and covered by health insurance.

New system for early approval and insurance system



[Reference materials]

Proper evaluation of medical technology and reform of the health insurance system

⇒ Possibility of selective treatment (combined treatment not covered by insurance)

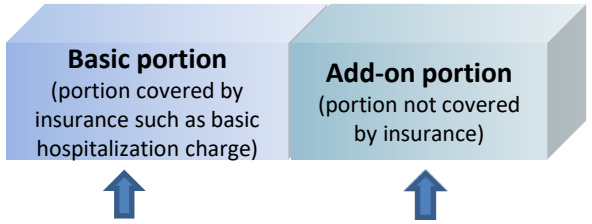
Non-insurance combined treatment system

Created by amendment of the act in 2006
(Scope expanded from Specified Medical Care Expenses)

Medical treatment that can be used in combination with health insurance

1 Evaluative medical treatment ⇒ Assess for insurance introduction
2 Medical treatment by patient 's request ⇒ Assess for insurance introduction
3 Selective medical treatment ⇒ Not premised on the insurance introduction

Structure of Medical Expenses Combined with Treatment Outside Insurance Coverage
[Cases of Evaluative Treatment]



Benefit covered by health insurance as combined medical expenses not covered by insurance

Fees can be collected from patients (Free fee)

* For medical expenses combined with treatment outside insurance coverage, the requirements for collecting fees from patients (such as posting of fees) are clearly specified.

- **Evaluative medical treatment**

Advanced medical
Medical treatment related to clinical trials of pharmaceuticals, medical devices, regenerative medicine products, etc.
Use of pharmaceuticals, medical devices, and regenerative medicine products that have not yet been covered by health insurance after being approved by the Pharmaceutical Affairs Law
Off-label use of drugs listed in the National Health Insurance drug price list
Non-applicable use of insurance-covered medical devices and regenerative medicine products

- **Patient request medical treatment**
- **Selective medical treatment**

Special recuperation environment (different price bed)
After-hours medical care
Appointment treatment
First visit/return visit at a large hospital
Hospitalization for 180 days or more
, etc

Current status

- There is a big gap between the evaluation of new technology using diagnostic and therapeutic equipment in Japan and the evaluation overseas. As a result, some companies gave up insurance coverage. (Examples: Diagnostic equipment testing, malignant tumor gene testing, PET testing, etc.)
- Innovative products are approved under PMD act and are being used in medical settings. However, it rarely leads to addition of medical fees, etc. In order to revitalize development, it is necessary to recover development costs.
- In the supplementary opinion for the 2022 revision, it was clarified that the government will continue to consider appropriate evaluations of pharmaceuticals, medical devices, and medical technology, while understanding the status of discussions on the scope of insurance benefits.

[Issues]

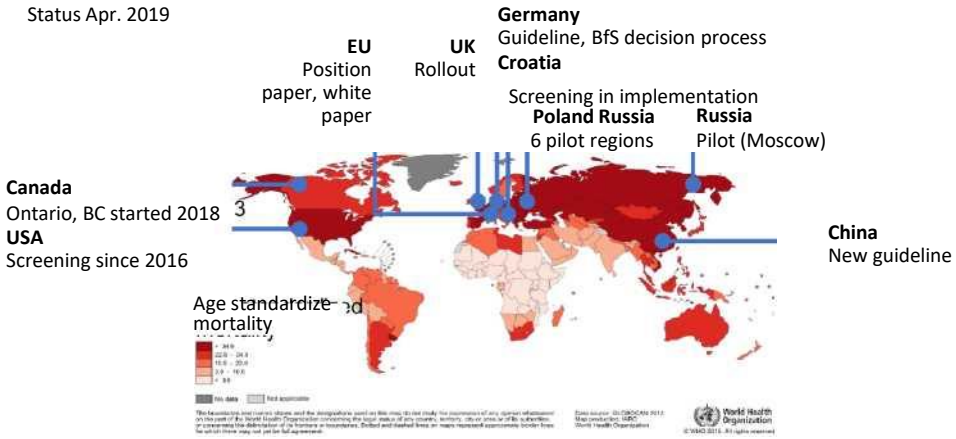
•Appropriate innovation technology evaluation is essential for stable supply to patients. There are products that are marketed but have a negative spread, and products such as SiMD that are difficult to reimburse with the cost of the technology applied mutatis mutandis in Japan.
How about considering the products such as these products that contribute to the convenience of patients (for example, the patient's burden of the equipment cost in online medical treatment) as a framework for medical treatment combined with non-insurance?

3. Evaluation of medical device (medical technology) innovation
- Promotion of preventive medicine

Promotion of preventive medical care is expected to contribute to patients.

Low-dose lung cancer CT screening

- Promotion of incentives for preventive medicine similar level to overseas is expected to contribute greatly to reducing medical expenses and improving health (QOL) toward the era of 100-year life in Japan.
  - It is possible to extend healthy life expectancy by preventing aggravation and preventing illness (pre-disease) before it occurs.
  - Low-dose lung cancer CT screening is used as a preventive measure in the insurance system, etc. in Europe and the United States.
  - In the United States, health insurance-funded screening is available for smokers over the age of 50.
  - In some local governments, lung cancer screening is performed by CT, but in many local governments, lung cancer screening by X-ray photography has been carried out for a long time.
- Is it possible for the Ministry of Health, Labor and Welfare to appeal to local governments nationwide to make low-dose lung cancer CT screening an essential item for lung cancer screening under specific medical examinations and specific health guidance in Japan?



SaMD equivalent to Class I (health claim)

- SaMD has a program equivalent to Class I aimed at public prevention, recurrence prevention, and prognostic use, but it cannot claim that the public's healthy life expectancy can be expected.
  - Class I-equivalent programs are treated as non-medical devices, but may scientifically proven to "maintain health conditions or healthy activities" or "healthy lifestyles reduce certain chronic".
  - Can doctors, dentists, and pharmacists encourage the use of programmed medical devices in medical examinations, etc.?

Electric RFID toothbrushes

[cannot declare]
- Prevention of gingivitis and periodontitis

Smart sleeve

[not recommended]
- People with sleep disorder