

FY2024 Public-Private Dialogue:
EBC Proposals

Public-Private Dialogue for the Creation of Innovative Pharmaceuticals, Medical Devices,
Regenerative Medicine, and Other Products

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EBC Medical equipment & IVD Committee

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1. The state of medical care in a social security system for all generations

- i) Securing social security financial resources and new mechanisms for providing medical care

First of all, in order to realize a medical care delivery system under social security for all generations in an aging population with a declining birthrate, we would like to ask for the securing of social security funds that take into account rising energy prices at medical institutions, uneven distribution of human resources and rising labor costs, as well as rising material prices, the impact of foreign exchange rates, and rising prices in the industry that supplies medical materials and medical technology.

In addition, in Japan, where device loss and radioactive PET examination loss are occurring just as much as drug loss, it is also an urgent task to create a new medical insurance system that can provide innovative medical equipment to patients from prevention to prognosis.

2. Evaluation of medical technology innovations

- i) Promoting patient access and utilizing Treatment of Patients' Choice (SENTEIRYOYO) and Treatments to be evaluated (HYOUKARYOYO)

[Current situation]

A new two-tiered insurance system was established based on the German system for programmed medical devices, which has been continuously advocated in public-private dialogues. However, it is not sufficient for rapid access to patients (it is limited to programmed medical devices with functions that have not been medically proven to be sufficiently useful). In this two-tiered approval and two-tiered insurance system, rapid market entry is required using evaluation treatment in the first tier. In the meantime, evidence is collected as application data for the second tier approval, and insurance coverage is required after final approval in the second tier.

In the field of treatment, while clinical trials by Japanese people are required, measures have been implemented to relax domestic phase I clinical trials on the condition that a framework for international collaborative clinical trials is established, but there is still a loss of diagnostic treatment due to the lack of progress in the introduction of products marketed overseas.

Public knowledge applications are only applicable to the expansion of application of products that have already been approved in Japan, but there is a system in which insurance coverage precedes pharmaceutical approval. (There is a system in which mixed medical treatment is not required)

[Issues]

With regard to restructuring the two-tier insurance system, we would like to see the creation of a system that can expand the scope of coverage, taking into consideration patient access in the first tier, and continue to consider adopting a framework such as Treatment of Patients' Choice expenses that would allow continued use of the product due to its proven use by patients if a decision is made after drug and device approval in the second tier that the product does not qualify for insurance coverage.

Why not adopt a breakthrough insurance system, such as that used by the FDA, as a fair

evaluation of innovative products, while considering patient convenience?

Could we consider a system that allows approval and insurance coverage through publicly known applications for programmed medical devices, etc.?

ii) Promoting preventive medicine to prevent illness from worsening

Promoting preventive medicine is expected to contribute to patients.

- Low-dose lung cancer screening

In order to realize social security and health checkups for all generations, it is urgent to promote and popularize preventive medicine and health checkups, with reference to overseas examples, to strengthen the sustainability of the medical system and promote health by reducing medical expenses in preparation for the 100-year lifespan era.

- Preventing serious illness and preventing illness (pre-illness) will extend healthy lifespan.
- Low-dose lung cancer CT screening is used preventively in insurance systems in Europe and the United States.
- In the United States, insurance-covered examinations are conducted on smokers aged 50 and over.
- Some municipalities conduct lung cancer screening using CT, but many municipalities have been conducting lung cancer screening using X-rays for some time.

Should we consider introducing low-dose lung cancer CT as a mandatory item for lung cancer screening in preventive screening for high-risk individuals?

- Class I SaMD health claims

SaMD has a Class I equivalent program aimed at use for prevention, recurrence prevention, and prognosis for the public, but it cannot claim that it will contribute to the public's health and longevity.

Class I equivalent programs are treated as non-medical devices. Is it possible to make certain claims (health claims) when scientific evidence can be shown that "maintains health and healthy activities" or "a healthy lifestyle reduces the condition or risk of certain chronic diseases"?

Can doctors, dentists, and pharmacists encourage the use of the product during health

checkups, etc.?

3. Expansion of remote medical care

i) Evaluation of the contribution to patients through work style reforms for medical professionals

[Current situation]

- Remote medical support

Online medical consultations and medication consultations, which were lagging behind other countries, have been expanded as an emergency response to COVID-19, improving patient convenience. We hope for further expansion.

Remote doctor-to-doctor diagnosis and treatment, remote centralized ICU management, etc. are expected to become more widespread as they contribute to the equalization of medical quality for patients and the reduction of the burden on medical professionals, given the limited medical resources. In Japan, remote diagnosis is only used as a tool to give instructions on operation through communication. In addition, in the case of remote ICUs, e.g. considering the burden on the supporting medical institutions, the insurance evaluation is not necessarily sufficient.

These uses will help to make up for the absolute shortage of specialists and the relative shortage due to uneven distribution, and will help to solve social issues such as responding to work style reforms for medical professionals.

In addition, they are effective in improving and equalizing the quality of medical care and ensuring accessibility to medical care. Furthermore, they are expected to promote technological development in related fields in Japan.

[Proposal]

- Further promotion of remote medical care and digital health.
- We would like to ask for continued discussion so that remote medical care can be introduced without hesitation in clinical settings, with a view to further societal implementation.
(Examples: D-D remote medical treatment operation support system, D-D remote

diagnostic imaging operation support system, etc.)

- We would like to ask for further consideration of an evaluation framework to promote the spread of centralized management by specialized medical professionals, such as remote ICUs, in Japan.

[Reference material]

Promoting the creation and use of a medical device product database - from the medical field to tracking patient usage records -

Further utilization of medical safety and promotion of the construction of product databases for pharmaceuticals, medical devices, etc. that contribute to the efficiency of administrative work at hospitals, etc.

- A system that allows implanted device information to be checked at medical institutions nationwide
 - A system that allows implanted device information to be checked when transferring to another hospital or undergoing MRI imaging in an emergency
- A system that allows patients to view their own implanted device information
 - A system that allows patients to view their own implanted device information via PC, smartphone, etc.
- A system that allows medical device usage records to be used as big data for data analysis

