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Proposal for Ensuring Access to Advanced Medical Devices and Promoting Sound Finances for Medical Insurers

- Constructing a Reimbursement System for Medical Supplies Premised on Value-Based Health Care -

AMDD had developed a proposal on creating a reimbursement system that measures the value of innovation to then be reflected in pricing. The proposal also includes recommendations for creating a resource investment framework that focuses on high-value medical devices and innovation, with the goal of “promoting innovation and ensuring access to medical care for patients” and “promoting sound finances in health care and nursing.” (Please see the following pages for specific details of the proposal.)

Measuring the Value of Innovation and Reflecting the Value in Reimbursement Prices

AMDD believes we should aim to achieve more efficient health care, not by seeing medical devices as mere costs, but by making full use of their innovation, while maintaining patients' access to health care as much as possible. To accomplish that goal, we need a reimbursement system that properly measures the value of innovation and reflects it in pricing, and a resource investment framework that focuses on high-value medical devices and innovation. This approach is in keeping with global trends; and by encouraging high-value innovation, we believe we can achieve an environment in Japan that will foster the creation of globally competitive medical devices.

The Japanese market for medical devices is worth approximately 2.7 trillion yen, which accounts for only about 7% of the national health care expenditures, yet advanced medical technologies developed by innovation save lives, act on behalf of lost functions, and improve QOL after treatment. The innovation of medical devices improves continuously supporting governmental initiatives, such as extending healthy life expectancy, increasing productivity and reducing early retirement for nursing care. We consider that expenses for medical devices should be evaluated extensively and comprehensively from social standpoints. This should

be done not only by considering the price of medical devices themselves, but also from the perspective of the productivity loss of patients and caregivers, including indirect costs of medical devices, and by quantifying such prices, productivity, and costs. By fostering medical device innovation to achieve more efficient medical care, it should be possible to create even greater benefits for Japan in terms of medicine and economics.

Limiting Medical Device Costs During Transition Periods

A number of measures aimed at promoting the soundness of health care finances have been instituted, and a reduction in unit prices for medical devices has also been implemented through measures that include the FAP (Foreign Average Pricing) system. We at AMDD believe that making it difficult to invest in innovation by further reductions in unit prices, limiting patients' access to health care by excessive restriction of indications and facility standards, and being too careful in widespread use would not be a wise policy if we wish to keep Japan's health care system and finances sustainable for the future.

Given this goal, it is necessary to design an appropriate valuation system based on the distinctive characteristics of medical device innovation, which differs from pharmaceutical products. Based on this awareness, AMDD has developed ideas for providing future valuations based on the value of medical devices, and for determining a clear distribution of resources within a limited budget. This can be done from both perspectives of maintaining a sound medical insurance system and continuing to promote innovation. We strongly hope that this will be an opportunity to start discussions with the people concerned.



Mr. Kosuke Kato
Chairman, American Medical Devices and Diagnostics
Manufacturers' Association (AMDD)
Managing Director,
Edwards Lifesciences Corporation

1. Promotion and rapid introduction of innovation, as well as securing patient access to healthcare

A value based evaluation of medical devices is necessary, centered around clinical efficacy delivered to the patient and benefits to the family providing care. To this end, value largely stems from aspects such as invention/innovation, and so efficient and accurate criteria assessing these will allow effective devices to rapidly enter the medical setting and provide reliable access to healthcare (i.e. opportunities to receive accurate care).

- Medical devices are known to provide long-term sustained care for the patient, and devices such as prosthetic joints/limbs, pace makers, intraocular lenses are prime examples which support the patient's ADL (Activities of Daily Living).

- More recently devices which contribute to prevention/diagnosis are gaining traction, such as a diagnostic device which monitors cardiac function, assessing the formulation of blood clots which may lead to stroke, thereby providing early indications for treatment. This in turn has led to the support of patient ADL, reductions in necessary future care and treatment costs.

1.1 Introduction of a price adding system based on extensive economic assessment (①)

In addition to conventional criteria such as efficacy and safety, we would like to propose methods that assess, from an economic perspective, the contribution a device makes in optimizing resources for health and nursing care.

- Currently, additions for innovation and additions for usefulness are evaluated from three points of "new mechanisms", "efficacy and safety", "improvement of the method of treatment". We propose to add “economics” standing in the value as a new requirement for compensated additions.
- “Economics” should assess not only the cost for treatment, but also the savings on nursing care costs and burden for caregivers.
- In the case of evaluating innovation from an economic perspective, pricing will be determined based on the Japanese healthcare market environment, and so the device should be excluded from the foreign price re-pricing policy.

1.2 Creation of a to-be-proven forerunner assessment policy (②)

In order to realize rapid promotion of innovation, we propose a “to-be-proven forerunner assessment” policy whereby devices are evaluated based on clinical data (efficacy, safety and economics) collected post-launch.

- All too often, medical devices are unable to collect sufficient clinical data at the time of launch. And due to the long-term effect of treatment, devices often require a prolonged assessment period. In order to ensure rapid access to cutting-edge treatment, assessment and pricing at the approval stage based on probabilistic efficacy, safety and economic viability can be regarded as a reasonable approach.
- Devices that attain forerunner assessment will be re-assessed after a certain period post-launch based on finding from post-launch clinical study schemes which may utilize publically available database, etc.
- If data collected during the post-launch clinical study do not meet the initially expected efficacy, safety or economics, the price added due to the “forerunner premium policy” may be reduced.
- In the case of evaluating device for a forerunner premium from an economic perspective, pricing will be determined based on the Japanese healthcare market environment, and so the device should be excluded from the foreign price re-pricing policy.

1.3 Creation of a post-launch C1/C2 re-application policy (③)

For specifically insured medical treatment materials included in existing functional subdivisions, allow for a re-assessment of functional subdivision based on clinical and/or

economic data collect post-launch through the creation of the “post-launch C1/C2 re-application policy”.

- If clinical data/study results post-launch show aspects (efficacy, safety, economics etc.) that were not evaluated during reimbursement listing, the company may apply for re-assessment of the product.
- In the instance where product economics are re-evaluated through the C1/C2 re-application policy, pricing will be determined based on the Japanese healthcare market environment, and so the device should be excluded from the foreign price re-pricing policy.

2. Fiscal improvement of healthcare/nursing care medical devices/treatment material policies

In order to improve the fiscal efficiency of Healthcare and Nursing care, expenditure cuts must be driven through effective management of listed reimbursed products in addition to improved economics from innovative medical devices. The savings must then be re-invested into driving further innovation.

2.1 Increased inclusion range for treatment materials within technical fees (④)

Medical devices/treatment materials with relatively low-price and standardized quantity per procedure may be considered for inclusion within technical fees from simplifying reimbursement policy perspective.

- If STMs are to be included in technical fees, corresponding technical fees should be increased by the amount equivalent to STM reimbursement price.
- It is necessary to involve members of Academia, Government and Industry when considering “device inclusion”.

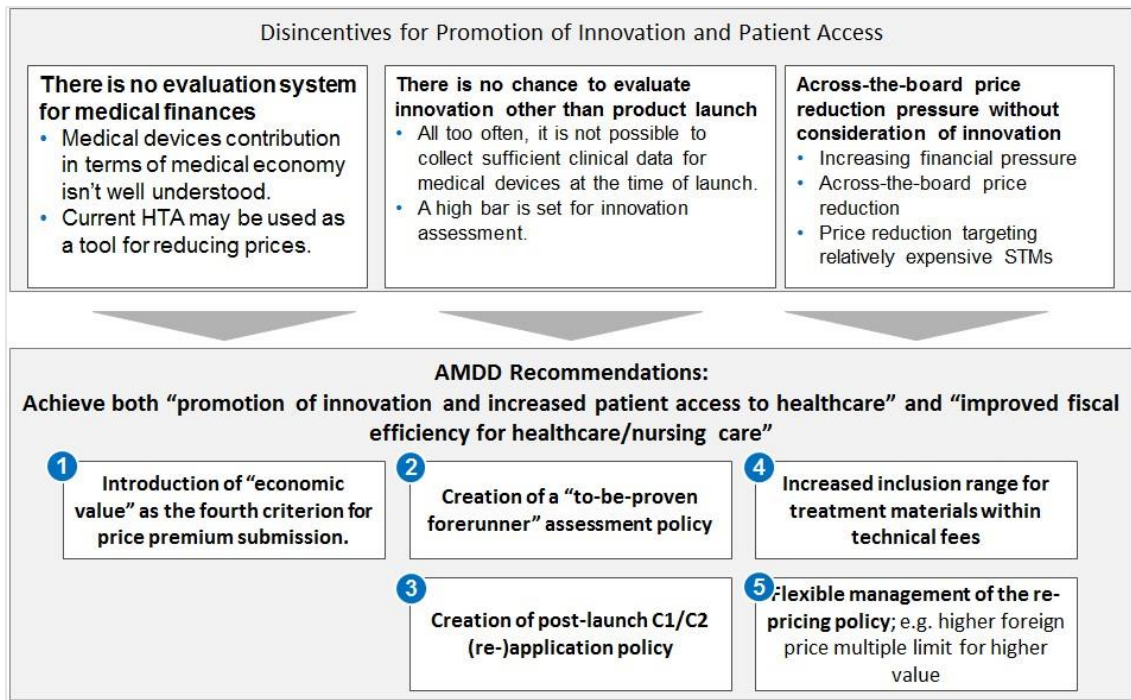
2.2 Flexible management of the re-pricing policy (⑤)

Although AMDD is against the foreign re-pricing policies that fail to capture differences in healthcare systems among referencing countries, we propose conventional re-pricing policies to employ more flexible management approaches. These approaches include utilizing differing coefficients to conventional re-pricing depending on functional subdivisions etc.

- In the case a subdivision is established for specifically insured medical treatment materials, foreign price adjustments will be made in the initial assessment, and so any re-pricing post-division establishment should exclude foreign price re-pricing policy for several revision cycles.
- We propose raising limit of foreign price magnification for functional subdivisions consistently introducing new devices, as is the case with subdivisions determined to have strong medical demand through conferences such as “The commission to determine rapid introduction of high-demand medical devices”.
- Concomitantly, for subdivisions that have experienced a reasonable time since creation without having new products over a set period of time, we propose a lower foreign price magnification limit provided benchmark and average all available foreign prices

(nevertheless, in the case where the market is niche and thus product development is limited, the effect on supply sustainability should be taken into consideration).

Image of Value-Based Reimbursement System



Examples of the Innovation of Medical Devices

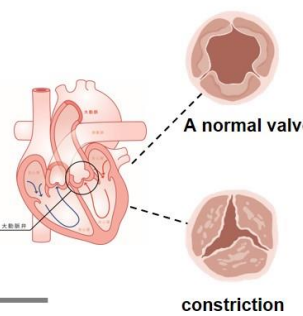
TAVI

Aortic valve stenosis


- A type of "valvular heart disease" in which the aortic valve becomes hard and it does not open sufficiently.
- Symptoms: Shortness of breath and fatigue
- Mortality rate within 2 years is 50%. ^{*1}
- Approximately 30% of patients neither can have nor had an open chest surgery for some reason. ^{*2}

Treatment:

TAVI (Transcatheter Aortic Valve Implantation)



- Compared with surgical valve replacement, using conventional thoracotomy and artificial heart-lung, it is less invasive, because the valve is implanted through the blood vessel.
- We can also treat elderly patients who could not be cured completely or patients with other diseases.



*1. Otto CM. Timing of aortic valve surgery. Heart. 2000;84:211-218. *2. Pelikka et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up.

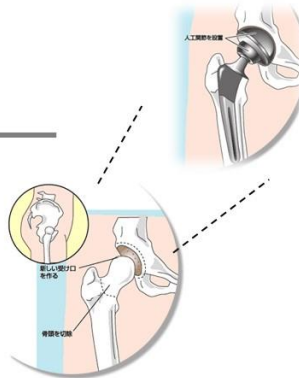
Artificial Hip Joint

Osteoarthritis and Femoral neck fracture etc.

- Disability of hip joint, pain, and restriction in range of motion occurs.
- Symptom: Not able to hold heavy things, walk long distances, go up and down stairs, put socks on, cut nails etc.
- Treatment: In cases where treatment such as medicine (conservative therapy) does not improve the situation, the hip joint replacement is performed by surgery.

Treatment: Artificial hip joint replacement

- The hip joint is replaced with an artificial joint by surgery.
- The movement of the hip joint improves after the operation, and the pain of the hip disappears.



Insulin Pump with Personal CGM Function

Diabetes

- Diabetes requires routine measurement of blood glucose level, but in the past it was possible to measure blood glucose only with intermittent measurement by puncture.
- Severe patients need to perform self-injection treatment of insulin based on the measured blood glucose level.

New technology: Insulin pump with personal CGM function

- Personal (real-time) CGM function is installed in insulin pump.
- It continuously captures blood glucose fluctuation with a line and helps to achieve optimal blood glucose control without increasing the risk of hypoglycemia.
- It informs the excessive increase or decrease in blood sugar level regularly.

Personal
(real-time) CGM



Insulin pump

AMDD Holds 8th New Year's Party

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held the New Year's Party at the Sakura-no-ma of the Imperial Hotel on January 12. In the greetings at the beginning of the party, Mr. Kosuke Kato, Chairman of AMDD (Managing Director of Edwards Lifesciences Corporation) expressed his hope that "AMDD will actively focus on three pillars this year: reforming the evaluation of innovation, accelerating reviews, and contributing to industrial development in Japan." Regarding the evaluation of innovation in particular, he said that AMDD will develop a proposal for an insurance system for patients by again clarifying the differences between medical device innovation and pharmaceutical products, and by linking it to industrial development in Japan.

In the greetings from the guest, Ms. Noriko Furuya, Senior Vice Minister of Health, Labour and Welfare (MHLW), offered encouragement by saying that "the medical device industry is important as a growth industry and the Japanese government will give All Japan support to the development of medical devices." After, Mr. Andrew Wylegala, Minister Counselor for Commercial Affairs at the Embassy of the United States of America, and Mr. Koji Nakao, Chairman of the Japan Federation of Medical Devices Associations (JFMDA), gave their greetings. The New Year's Party then began with the participation of guests from all walks of life after Mr. Kenichi Matsumoto, Chairman of the Japan Association of Medical Devices Industries (JAMDI) proposed a toast.



Left: Ms. Noriko Furuya, Senior Vice Minister of Health, Labour and Welfare
Right: Kosuke Kato, Chairman of AMDD



New Year's Party

Value of Medical Technology

<Diagnosis and Treatment of Cancer>

Capsule Endoscopy Effective for Image Diagnosis of Small and Large Intestines

Capsule endoscopy is a process that uses a tiny capsule the size of a large vitamin pill. It can be easily swallowed and is used in a test that takes pictures of the mucous membrane of the gastrointestinal tract. Small bowel capsule endoscopy and large bowel capsule endoscopy started being covered by insurance in 2007 and 2014, respectively. They are relatively new imaging test technologies.

A capsule endoscopy system is composed of (1) a capsule endoscopy (for small and large intestines) with a built-in ultra-small camera that wirelessly transmits the images taken, (2) a sensor array and data recorder that receives the images, and (3) a workstation in which software is installed for interpretation and diagnosis.

Capsule endoscopy for the small intestine is a new testing method that sheds light on organs known as the “dark continent.” Since its arrival in Japan, many clinical applications of this endoscopy have been advanced. When it obtained pharmaceutical approval, gastrointestinal bleeding of an unknown cause was the only indication. But now, the indication of this endoscopy has been expanded to all diseases of the small intestine, including Crohn’s disease.

Capsule endoscopy for the large intestine has generated the value of satisfying unmet medical needs, for example, by providing patients who could not undergo colon fiberoscopy because of a physical difficulty and other reasons, with an opportunity to undergo a test. Since capsule endoscopy can be performed by physicians other than endoscopy specialists, it is expected that this method will spread to areas with scarce healthcare services and utilized for early detection and treatment of large intestine carcinoma, which is considered likely to increase in the future.

In a clinical setting, various efforts for proper use of capsule endoscopy have been made, including a large-scale post-marketing clinical study by registry, under the initiative of the Japanese Association for Capsule Endoscopy.



It is considered that in the future there will be advances in the clinical applications of capsule endoscopy, so that burdens on patients can be reduced and image recognizing technology can be improved to make it easier for doctors to interpret the images.

(Article written with full responsibility by Go Ikeda, Medtronic Japan Co., Ltd.)

Left: Large bowel capsule endoscopy
Right: Small bowel capsule endoscopy

AMDD Holds a Lecture for Member Companies - Diversity and Women's Success -

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held an Internal PR Meeting on "Diversity and Women's Success" in Tokyo on December 8 last year. The target for this lecture was persons in charge of or related to public relations/communication and personnel affairs from member companies. This meeting is every year to deepen people's understanding of AMDD activities and to exchange information among AMDD member companies.

In the 5th meeting in 2016, the results of the survey on "diversity" which had been conducted for AMDD member companies beforehand were presented. Ms. Kathy Matsui, Vice Chair of Goldman Sachs Japan, who advocates womenomics, delivered a special lecture titled "Womenomics 4.0: Time to Walk the Talk." Also, three companies on behalf of AMDD member companies introduced examples of their efforts for diversity in the workplace. Inspired by Ms. Matsui's strong messages and the various examples of other companies, participants renewed their pledge to work on promoting diversity.

The AMDD Diversity Working Group, which started its activities, such as a survey, last year, will continue to get actively involved in various efforts, including external ones, aiming to promote diversity within AMDD.



Left: Ms. Kathy Matsui

Right: Presentation of the Survey from the Public Awareness Committee