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NEWSLETTER

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Now is the Time to Accelerate the Development and Recognition of Innovative Medical Devices

As the consumption tax hike was postponed again, medical service fees will not be revised and a price survey on special treatment materials will not be conducted this fiscal year. It is very pleasing that the foreseeability of the Japanese market has been maintained and that there will be no change in reimbursement prices this year.

Meanwhile, it is not easy to comprehend figures with a large number of digits. Do you have any sense of the scale of one trillion yen, which can be expressed in only three words? If you piled up 10,000 yen notes so that they amounted to 1 trillion yen and then pushed the tower over on its side, how long would it be? Let's assume you start at Kasumigaseki, where the Ministry of Health, Labour and Welfare is located. If you stacked up one hundred 10,000 yen notes, the thickness of the pile would be about 1 cm. The distance from Kasumigaseki to Shinjuku is 5 km, and to Kasai Rinkai Park, which is located next to Disneyland, it is 10 km. In fact, a line of 10,000 yen notes that is equivalent to 1 trillion yen would go from Kasumigaseki to Kasai Rinkai Park. This is a substantial amount of money!

Consider from this perspective that a consumption tax hike of 1% leads to tax revenue of about 2.5 trillion yen and this tax revenue was supposed to be used to cover the cost of social security, it is difficult to decide whether we should be pleased with the postponement. As medical costs in Japan are increasing by about 1 trillion yen every year, the voices calling for suppression of these costs are expected to become stronger.

On the other hand, in response to the postponement, we can now focus on how to establish a policy support system that makes it easier to discover and popularize innovative

medical devices, with an eye on the revision of the medical service fee system in 2018. However, based on the above situation, it seems likely that there will be much greater pressure to curb medical costs in the next revision.

Therefore, in creating a new system, better designed ones, such as those that can provide incentives for the promotion of innovations or can be demonstrated to suppress medical costs for each disease, will become important. We must reinforce the policy of paying a reasonable reward for special treatment materials that increase benefits for individual patients such as better prognosis and less invasiveness. But at the same time, we must have a perspective on how to introduce and utilize devices, in a broad sense, that can macroscopically improve the quality of medical care such as its safety, the prevention of infections, an increased efficiency of care that utilizes IT and efficient use of medical resources, based on remote medicine, and with an eye on the entire system of social security. I am looking forward to hearing your proposals and discussions during this period so that we can form a framework for such ideas and flesh out evidence and conceptual images for specific practice.

Mr. Kuniaki Miyake
Director of the Office for Medical Device Policy, Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare

Mr. Kuniaki Miyaki started working for the Ministry of Health and Welfare (currently Ministry of Health, Labour and Welfare) after graduating from the Keio University School of Medicine in 1995. He assumed his current position in 2015 after working as an Assistant Director of the Research and Development Division, Health Policy Bureau; Assistant Director of the Health Science Division, Minister's Secretariat; Assistant Director of the Tuberculosis and Infectious Diseases Control Division, Health Service Bureau; and Advanced and Special Medical Advisor in the National Hospitals Division, Health Policy Bureau, Ministry of Health, Labour and Welfare.

Revision of the Medical Service Fees in Fiscal 2016

In the revision of medical service fees in April this year, various changes to the insurance reimbursement system for medical devices were made. Of these changes, significant ones are reported here.

Specific Nature of System Reform

(1) Review of comparison level of the foreign price reference system

In this revision, the comparison level with foreign average prices was lowered to 1.3 in principle, for the foreign price adjustment of newly listed products and the recalculation of listed products. The method of calculating foreign average prices by recalculation was also adjusted, and if there is a large variation in prices among reference countries, high prices are excluded from the calculation.

(2) Evaluation of Innovations

Products developed in response to a request from the committee on early introduction of medical devices with high medical needs (Needs Committee) are subject to a special exception to functional categories, and the comparison level with foreign average prices for such products is set at 1.5. In addition, any product with an insurance application submitted after such products are also subject to the special exception to functional categories to provide an incentive for developer companies.

(3) Acceleration of Insurance Listing

To list a new functional category, companies were previously required to obtain approval from the Central Social Insurance Medical Council by the end of the second month before the month of listing. This rule was changed in April this year so that categories approved by the Central Social Insurance Medical Council by the end of the month before the month of listing will be listed.

(4) C2 (New Function/New Technology) Category

It is now clearly defined that companies can apply for improved technologies using medical devices in the C2 category, and a dedicated organization for treatment materials can make proposals on the technical fee of such new technologies at the general meeting of the Central Social Insurance Medical Council.

Trial Introduction of Cost-Effectiveness Evaluation

A cost-effectiveness evaluation, which has been discussed by the Central Social Insurance Medical Council since 2014, started being introduced on a trial basis in April this year. In the trial period, cost-effectiveness is evaluated and reflected in reimbursement prices for listed products. And at the same time, a similar evaluation is also conducted for newly listed products to examine how cost-effectiveness can be incorporated into the system.

In-Vitro Diagnostics (IVD)

As there has been no definitive place for discussions to take place on IVD in the framework of the Central Social Insurance Medical Council, the industry has demanded that a place to state opinions be clarified. This category of products will be handled in the Special Committee on Materials in the Central Social Insurance Medical Council from now on.

Looking Back on the Revision

The medical device industry has long called for the proper evaluation of innovations, improvement of predictability, and abolition of a recalculation system. We consistently made such requests when submitting opinion statements and on other occasions to the Central Social Insurance Medical Council for the revision in fiscal 2016.

In this revision, system changes that could promote innovations, including evaluation of products developed in response to a request from the Needs Committee, were made. It was also approved to continue mechanisms that evaluate products for their prompt introduction and special exceptions to functional categories, which were established in the previous revision. We welcome that particular consideration was given to the evaluation of innovations.

On the other hand, our request for a foreign reference price system (abolition of the system, or if abolition is difficult, similar operation) was not accepted despite our long and consistent demand. This resulted in a reduction in the comparison level of and change in the method of calculating foreign average prices.

The medical devices industry has consistently claimed that the recalculation system, which only compares prices in foreign countries that have a different market environment, is not appropriate. Changing the rules at every revision significantly compromises predictability, and furthermore, comparisons with foreign prices are largely influenced by fluctuations in the currency exchange rate, which is not directly related to the medical environment. In view of these problems, our industry strongly wants this system to be abolished.

Future Issues

For the evaluation of innovations, the system itself is improving, but in some cases, the evaluated results are reversed without being sustained due to a review of functional categories, foreign price adjustment or recalculation. It is necessary to propose a system that can yield a virtuous cycle in which innovations are properly evaluated and as a result new ones are encouraged.

To evaluate cost-effectiveness, its role is fully understandable from the perspective of having effective utilization of medical resources, but the trial introduction has started before details of the evaluation system are clearly defined. When details of the system are determined in the future, a thorough discussion about the evaluation of the value of medical devices and technologies using medical devices should be warranted. The industry should also examine how the value of medical devices and technologies using medical devices can be evaluated to make constructive proposals.

Mr. Toshifumi Hayashi
Director of Government Affairs, Zimmer Biomet G.K.

Patient's Voice
ERAS by Early Postoperative Enteral Nutrition (PEG/PEJ) Improves the QOL of Patients Following Total Gastrectomy

Mr. Teruaki Aoki
Visiting Professor, The Jikei University School of Medicine
Consultant for the Association of Gastrectomy Patients (Alpha Club)

Current Situation and Issues of Stomach Cancer Treatment in Japan

The leading cause of death among Japanese is cancer. Cancer morbidity is rapidly increasing for lung cancer, and it also continues to increase for stomach cancer. However, the number of deaths from stomach cancer (2013) shows that there has been significant improvement in the survival rate (from 2011 to 2013), although the number of deaths from lung cancer is showing a rapid increase in both morbidity and mortality. The 5-year survival rate of stomach cancer is currently between about 60% and 70%, showing that it is more easily "curable" than lung cancer and pancreas cancer.

On the other hand, patients whose postoperative quality of life (QOL) for activities of daily living (ADL) is significantly reduced are rapidly increasing, because too much attention is paid to the immediate outcome, which is "cancer cure." Further, mid- and long-term sequelae (aftereffects of a disease) that may occur due to the loss of the stomach are left untreated.

I will not go into the details of the progress of physiological research on the stomach here, but patients do not receive a full explanation before surgery. Hence, they do not recognize that a series of post-gastrectomy disorders always occurs in some form when there is a total gastrectomy as radical cancer treatment. These disorders occur in the order of a loss of the stomach, ghrelin depletion (appetite loss/eating disorder), reduced secretion of growth hormone (reduced systemic metabolism) and acceleration of aging (sarcopenia, nutrition disorder). Patients are also overly concerned with "treating cancer first," and according to our survey, less than 30% of patients are interested in what losing their stomach would mean before or immediately after surgery. A large number of patients are also discharged from hospital without knowing what kind of symptoms will occur. Moreover, an insurance system called Diagnosis Procedure Combination (DPC) encourages early hospital discharge. Patients are forced to be discharged from hospital when they need postoperative eating training and rehabilitation the most, and left with everyday eating issues that they cannot solve.

Enhanced Recovery Following Surgery (ERAS)

The concept of ERAS has spread mainly in Europe. It seeks to minimize the number of days of hospitalization, enable early social rehabilitation, and in social terms, reduce medical cost without impairing the safety of patients. It does this by improving the following three elements: 1) surgical stress reaction, 2) prevention of surgical complications and (3) promotion of postoperative recovery. Basically, this concept should be in harmony

with the government policy for reducing medical costs. I do not know the situation with regards to surgery in other sites, but at least for gastrectomy, the third element has not been achieved at all, and what is even worse, the situation has retrogressed to an inadequate level.

What should we do? I would like to make a brief proposal here. An enteral nutrition fistula (button type that does not disturb ADL) should be created at the "same time" as a total gastrectomy. Also, starting immediately after surgery, appetite loss and physical oral intake disorders should be relieved by giving patients enhanced nutritional therapy to supplement their sufficient calorie intake, followed by physical strength enhancement and eating rehabilitation. According to my personal experience, some patients who underwent a total gastrectomy using this approach 10 years ago or so have experienced no body weight loss and achieved early social rehabilitation, and some of them have been found to still be active over the age of 80 in a follow-up survey. Abolishing insurance coverage restrictions related to a simultaneous enterostomy and its popularization will save on the medical costs associated with postoperative disorders.

Voice from the Local Government

Kanagawa Prefecture's New Policy Initiative, "New Healthcare Frontier"

Kentaro Yamaguchi
Director-General for Healthcare New Frontier Promotion, Kanagawa

To overcome the super-aged society, Kanagawa is pushing forward with a "Healthcare New Frontier" policy that integrates the following two approaches: pursuit of state-of-the-art medicine and modern technologies, and improvement of ME-BYO, a pre-symptomatic state. As one of such efforts, the Kanagawa Medical Device Regulatory Science Center was established in September 2014 to accelerate the practical application of cutting-edge medical devices. This center conducts research on safety and efficacy evaluation, offers development support and nurtures human resources to develop state-of-the-art medical devices in collaboration with Yokohama National University, which is experienced in the research and development of pioneering communication technologies.

We also launched a "consortium" in which 44 companies and organizations participate. This consortium works on establishing test and evaluation systems required for assessing the safety, efficacy and quality of medical devices being developed by each company, while exchanging information mutually.

In our monthly "General Meeting" in which consortium companies and organizations participate, researchers, external experts and companies offer lectures on themes such as the development of medical devices to advance the cultivation of human resources. The meeting also offers development support to accelerate regulatory approval by providing the

advice of researchers from Yokohama National University or other academic institutions with regards to medical devices being developed by companies.

We also advance an effort toward "medical-engineering collaboration" by taking advantage of the characteristics and strengths of Kanagawa, which has two special zones—the Keihin Coastal Area Life Innovation Comprehensive Special Zone, in which many research institutions and related companies are located, and the Special Zone for the Robot Industry in Sagami, in which small- and medium-sized companies with a high level of manufacturing capabilities participate.

Through this effort, we hold seminars and networking events with the cooperation of medical institutions and medical device manufacturers to provide a place to connect the needs of medical settings (needs) and technologies of manufacturing companies (seeds).

Unlike other types of devices, the medical device industry is bound by many regulations on development, and they discourage the new entry of small- and medium-sized companies. To lower this hurdle, we opened a medical device consultation desk to offer support including advice on problem solving.

For companies advancing specific efforts toward product commercialization, our dedicated coordinators offer support on pharmaceutical and business strategies to enable the early achievement of success in our "model project for medical devices development support (individual support)."

Through these efforts, Kanagawa aims to accelerate the practical application of medical devices researched and developed in Kanagawa and to help companies enter the medical devices industry.

AMDD Participates in Public-Private Dialogue

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) participated in the "5th Public-Private Dialogue for Discovery of Innovative Pharmaceutical Products and Medical Devices" convened on April 12 by the Ministry of Health, Labour and Welfare. This meeting was held for government personnel including those from the Ministry of Health, Labour and Welfare to exchange opinions with the industrial personnel related to pharmaceutical products and medical devices while listening to requests.

The pharmaceutical industry called for the abolition of a special repricing rule in the reform of the drug price system, which was introduced in response to the increased social security cost, opposition to the yearly revision of drug prices, and the importance of investing in the research and development tax system.

From the medical devices industry, the Japan Federation of Medical Devices Associations, AMDD and Medical Equipment Committee in the European Business Council in Japan participated. They announced their request on the following four issues: insurance reimbursement system to promote innovations, improvement of development and application environment, promotion of ICT in medical care, and promotion of globalization.

From AMDD, Chairman Kosuke Kato (Managing Director of Edwards Lifesciences Limited) attended the meeting. He emphasized the necessity of value-based price settings and asked for the proper introduction of HTA, as well as the abolition of a foreign price reference system (FAP), which has long remained an issue, so that innovations for medical devices can be adequately evaluated.

For the medical device industry, this meeting was held for the first time in the past year. The form of future meetings was also discussed on the day of meeting, and Mr. Shiozaki, Minister of Health, Labour and Welfare, commented that meetings should be held as places where constructive discussions can take place by theme such as pharmaceutical products, medical devices and reproductive medicine. The government side will conduct deliberations related to the next meeting.

Left: Mr. Kosuke Kato, Chairman, AMDD on the very right
Right: During dialogue

Value of Medical Technology <Cancer>

Prostate Specific Antigen

Prostate specific antigen (PSA), which is a protein produced in the prostate, is an essential test marker (tumor maker) for the diagnosis and treatment of prostate cancer. The prostate is a male-specific organ located below the bladder, and prostate cancer is a type of cancer that grows in the prostate.

Prostate cancer often develops in a site distant from the urethra (marginal area) as shown in the illustration, and patients do not have subjective symptoms in the early stage. When symptoms develop, cancer may have migrated to the peripheral area of the prostate or other organs. Therefore, various test methods for early detection have been devised.

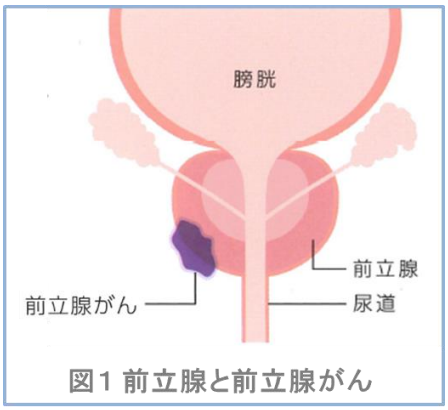

図1 前立腺と前立腺がん

Among them, the PSA test is commonly used for prostate cancer as well as clinical care (diagnosis and post-treatment follow-up). Because PSA is specific to the prostate, its blood level is often elevated even in early cancer so it can easily be determined by a blood test.

The measurement system has also progressed, allowing more minute PSA levels to be detected. The limitation of measurement was about 0.1 ng/mL in the 1990s, but currently less than 0.01 ng/mL can be

measured. A change in PSA level below 0.1 ng/mL provides beneficial information to determine the course of treatment after a total prostatectomy or hormonal therapy.

According to a statistics report of cancer in 2015, the estimated number of patients with prostate cancer overtook that of lung cancer and became the largest. As the number of people with prostate cancer is expected to continue to increase further, there will be more opportunities to perform PSA tests.

The PSA test is regarded as a tumor marker that has drastically changed the system of providing clinical care for prostate cancer. Also in the future, we want people to understand the characteristics of PSA and appropriately apply it in the clinical field.

(Article written with full responsibility by Eiichiro Matsuzaka, Abbott Japan)

AMDD Holds Roundtable on Treatment Materials System

On April 13, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held a briefing session and roundtable on the treatment materials system planned by the STM Committee. This roundtable, which also included a briefing session on the revision of medical service fees in fiscal 2016, was the first meeting held for member companies only.

For the first half of the meeting, we invited Mr. Kuniaki Miyake, Director of the Office for Medical Device Policy, Economic Affairs Division, Health Policy Bureau, Ministry of Health, Labour and Welfare, as a guest speaker to explain changes related to medical devices in the revision of medical service fees in fiscal 2016. In the panel discussion conducted in the second half of the meeting, a total of six panelists including Mr. Miyake, Mr. Tomoyuki Miyasaka (Unit Chief in the Office for Medical Device Policy), AMDD Chairman and Directors exchanged opinions under the theme of "Strengthening the Structure of Economic Affairs Division and Industry to Make the Japanese Market More Appealing." We received many suggestions from the Economic Affairs Division as to how we should cooperate with them to highlight the requests of the medical device industry, making the roundtable valuable for both parties.

Left: Lecture by Mr. Miyake
Right: Panel discussion

Value of Medical Technology
Our mission is to make more people understand the unlimited potential of advanced medical technology and its contribution to the reformation of the Japanese medical care system

Note: All opinions in this newsletter are the personal opinions of the authors, and do not necessarily represent the opinions and activities of AMDD.