Comparison of Reimbursement Pricing Systems for Medical Devices in Japan and Other Countries

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Abstract

In this article, we discuss the current status of the reimbursement price system for medical devices in Germany, France, the UK, the US, and Australia, which are the reference countries for the "foreign price adjustment system" in determining insurance reimbursement prices, and also provide implications for Japan. While Germany, the UK, and the US generally have reimbursement systems where medical devices are reimbursed as part of lumpsum payment, in other countries, as with Japan's specified insurance medical devices, individual reimbursement prices are set. In countries that primarily implement lumpsum payments, there is a system of adding a certain period of reimbursement price increase to compensate for the decrease in medical institutions' revenue resulting from the price increase of improved products. In addition, there are other support systems for collecting clinical evidence, which serve as examples for future discussions in Japan to promote the appropriate introduction of new medical devices.

Keywords: medical devices, reimbursement pricing system, lumpsum payment, value-based pricing

JEL classification: **I28, K23, L51**

1 Outline and characteristics of reimbursement pricing systems for medical devices in other countries

1.1 Germany

The German health care system is based on a social insurance system in which approximately 87% of the population participates. Employees are enrolled in public health insurance (Gesetzliche Krankenversicherung), which is defined in Part 5 of the Social Code, on an occupational or regional basis. Employees above a certain income level, self-employed persons, civil servants, etc. are not obliged to join, but those who are not eligible for mandatory coverage are obliged to join private medical insurance, which is regarded as a de facto universal health insurance.[i] Public health insurance provides all medically necessary benefits in a comprehensive manner. There are two

i In principle, all people are covered by these public and private insurance programs, but those who are not covered by these programs due to poverty or other reasons are covered by social assistance (public funds) in accordance with the provisions of Part 12 (Social Assistance) of the Social Code and Part 8 (Assistance for Children and Juveniles) of the Social Code.

benefit principles: The "professional principle," which requires that benefits be commensurate with the general level of medical care and takes into account medical advances, and the "economic principle," which requires that benefits be provided in a cost-effective manner without going beyond what is necessary.

1.1.1 Reimbursement for Inpatient Care

In addition to Part 5 of the Social Code, the Hospital Funding Law and the Hospital Medical Fee Law provide the basis for hospital reimbursement. The Hospital Financing Act defines the framework for compensation of hospital costs, and the Hospital Medical Fee Act defines the specific mechanism. Under this structure, German hospitals are operated under a "dual financing system" and are financed basically from two sources. The costs of capital investment in hospitals are to be borne by the state as investment costs based on the state government's hospital plans and investment programs. While the costs of capital investment are generally excluded from reimbursement, recurring operating costs (personnel, drugs, various supplies, etc.) are covered mainly by public health insurance through a per-diagnosis grouping-based blanket reimbursement system (hereafter referred to as "DRG blanket reimbursement" [ii]). (Iwama, 2016).

The reimbursement system is positioned within a hospital-specific budget system. Each hospital negotiates annually with the health insurance fund (Krankenkasse) to determine the benefit structure and budget for each hospital. Based on the DRG evaluation coefficient data for the current year, the hospital negotiates and agrees on a budget for the type and amount of the comprehensive, additional, and other reimbursements for DRG cases to be implemented by the hospital in the following year, on a benefit basis. If there is an excess or deficiency between the budget and the income from reimbursement, an income adjustment is made.

Thus, within the budgetary framework, the DRG lumpsum payment system is used for budget agreements and ex post settlements. Budget negotiations are based on data from the DRG evaluation coefficient[iii], and revenues subject to revenue adjustments are calculated by the DRG lumpsum payment system (Tanaka, 2019).

1.1.2 Reimbursement for Medical Devices and Equipment

The DRG lumpsum payment encompasses the cost of all benefits for cases defined by the diagnosis group, and most medical devices and equipment are paid as DRG lumpsum payments.

Additional reimbursement covers benefits that cannot be properly paid by the DRGs, and the additional benefits will be included in the additional reimbursement catalog attached to the lumpsum payment agreement. This covers treatment of hemophilia, dialysis, blood products, and practices that use high-cost medical devices and therapies.

1.1.3 Examples of DRGs that Include Medical Devices

Table 1 shows examples of DRG classifications and reimbursement for percutaneous coronary intervention (PCI). The DRGs are subdivided according to the treatment, method, and patient

ii The DRG lumpsum reimbursement includes all inpatient medical expenses related to the relevant case. The difference is that DPC/PDPS in Japan only covers basic hospitalization charges, laboratory fees, drug costs, etc., and excludes surgery fees, medical devices used for surgery and high-cost drugs.

iii The maintenance and development of the DRG comprehensive system is legally stipulated to be carried out as a joint self-governing task of the Central Association for Disease Insurance, the Association of Private Medical Insurance, and the German Hospital Association. The Institute for Hospital and Medical Fee Research (InEK GmbH), which was jointly established by the three parties, is in charge of the research on the DRG system as a whole and the specific calculation of evaluation coefficients.

condition, and a reimbursement amount is defined for each.

First, reimbursement prices are determined by diagnosis and treatment, which are divided into three categories: Complex diagnosis (e.g., acute myocardial infarction), simple diagnosis (e.g., stable angina pectoris), and special procedures, and these are further classified by treatment method and by indicators to evaluate patient conditions.

Table 1.DRG Price List for Percutaneous Coronary Intervention (PCI) (2021)

Diagnosis/ treatment	Complex diagnosis (e.g., acute myocardial infarction)				Simple diagnosis (e.g., stable angina pectoris)				Special Procedures	
Treatment method	Three or more stents; and cutting balloon		Balloon catheter; 1-2 stents		Three or more stents; and Cutting balloon; 1 stent + IVUS/FFR		Balloon catheter; 1-2 stents		Rotablators, etc.	
PCCL*	PCCL greater than 4	PCCL less than 3	PCCL greater than 4	PCCL less than 3	PCCL greater than 4	PCCL less than 3	PCCL greater than 4	PCCL less than 3	PCCL greater than 4	PCCL less than 3
DRG (lumpsum payment)	F24A 9,829€ (9,829)	F24B 5,246€ (5,246€ in the previous year)	F52A 9,255€.	F52B 4,013€.	F56A 7,841€ (7,841)	F56B 3,788€ (3,788€ in the previous year)	F58A 6,473€ (6,473€ in the previous year)	F58B 2,921€ (2,921€ in the previous year)	F19A 11,903€ ($11,903)	F19B 5,981€ (5,981 million)

*PCCL: Patient Clinical Complexity Level, an index that evaluates a patient's condition based on complications and comorbidities.

1.1.4 Handling of New Medical Devices and Equipment

We will now look at the handling of newly approved products. The Federal Joint Committee (Gemeinsame Bundesausschuss: G-BA) is the main body that decides whether new medical technologies in the medical field are covered by insurance. The Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) evaluates the effectiveness and economic efficiency of health care systems and makes recommendations to the G-BA. In addition, Article 137c-1 of Part 5 of the Social Code stipulates that hospitals may provide new medical technology at the expense of the disease vault, unless the G-BA determines that the new technology is not necessary for the treatment of the insured person.

1.1.4.1 NUB (National Untimely Special Payment Scheme for New Innovations)

Newly approved medical devices are in principle paid as DRG lumpsum payments, but there is a special payment mechanism for a certain period of time through the NUB (Neue Untersuchungs und Behandlungsmethoden) mechanism when both the cost and the novelty of the product are high.

The NUB targets new breakthrough technologies that are not classified as DRGs, have been in use for less than four years, and whose costs cannot be covered by DRG reimbursement prices. The purpose of the NUB is to promote the use of new diagnostic and therapeutic technologies and to collect cost data.

The Institute of Hospital and Health Care Reimbursement (Institut für das Entgeltsystem im Krankenhaus: InEK) selects the applicable technologies, and medical institutions wishing to use the technologies negotiate with the disease vaults individually, including the availability and budget of the technologies. The target medical institutions are mainly university hospitals and other advanced medical institutions.

The term is renewable for one year, but after the NUB ends, new DRGs may be made or additions may be made, and so on.

1.1.4.2 Erprobungsstudie (Clinical Research Support Program)

In addition to the NUB, there is also a program (Erprobungsstudie) in which the government and companies provide funds to conduct clinical research on technologies that are expected to be effective and safe but are not covered by reimbursement due to lack of evidence. This is considered to be similar to the Advanced Medicine rule (Senshin Iryo) in the Japanese balanced billing reimbursement system.

This program may be based on applications from companies or designated by the G-BA. In the case of applications from companies, the G-BA will select which of the programs will be covered, and the costs associated with the research will be borne by the company and the costs associated with the treatment will be covered by the health insurance funds.

In the case of designation from the G-BA, the cost burden on the company will be limited, as it may be in the early stages of the NUB process described above or in checking the feasibility of the practice.

1.1.5 Quality Assurance and Evaluation

Quality assurance and evaluation is a task that many countries with lumpsum payment systems address. Germany also has a variety of initiatives, and, in relation to medical devices and equipment, each hospital is required to record defined "quality indicators" for specific benefits. Quality indicators, for example, in the case of pacemaker implantation, are defined as operative time, x-ray exposure time, perioperative complications, intracardiac signal amplitude, and in-hospital mortality. This data is aggregated and evaluated at the federal and state levels and fed back to each hospital. When peculiar data are discovered in the states, discussions are held or quality improvement measures are discussed with medical institutions (Matsumoto (2015)).

1.2 France

The French medical security system can be broadly classified into the compulsory "basic system" (public medical insurance), the voluntary "supplementary system" (supplementary medical insurance), and "universal medical benefits." Thus, the core of health care coverage is the medical insurance system. In addition to the general system for workers in the private sector, there are various occupational insurance systems, such as the self-employed social system for the self-employed and the agricultural system for farmers, which together with other systems based on the social insurance system achieve universal coverage. The supplemental system, which is the second level of the basic system, is a voluntary system that covers the portion of out-of-pocket expenses not covered by the basic system, but there is also a support system to reduce the burden of insurance premiums. Currently, more than 90% of the population is enrolled in some kind of supplementary system, which, together with the basic system, forms the foundation of the medical security system. Those who are not eligible for mandatory coverage under the basic system are covered by the universal health benefits system[iv].

1.2.1 Reimbursement for Inpatient Care

The reimbursement structure for services provided in medical facilities can be divided into

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iv Universal health care benefits are intended to provide free or near-free health care to those who for some reason are not covered by public health insurance or who are covered by public health insurance but are unable to sign a contract with a supplementary benefits organization (Matsumoto: Health Care System Reform, p. 103).

three main categories. The first is the cost of the hospital stay, the second is the cost of the services provided, such as surgical procedures and advanced treatments, and the third is the cost of expensive drugs and medical devices. For the first part, which accounts for the largest proportion of hospitalization costs, the fees for physicians, surgeons, obstetricians, and dentists are calculated as a comprehensive evaluation per hospitalization based on the diagnosis group classification (Groupe homogène de séjour, or GHS), the French version of DRGs. In principle, the cost of drugs and medical devices during hospitalization are included in the comprehensive evaluation, but the cost of surgery, procedures, and the use of certain expensive drugs and medical devices are paid on a piece-rate basis based on prices determined separately from the GHS.

1.2.2 Reimbursement for Medical Devices and Equipment

The EU Directive is the regulatory basis for approving the marketing of medical materials and devices. Medical devices are classified into four levels according to their level of risk. Class I devices, which have the lowest risk, can be sold only after the manufacturer itself sets the regulatory level, while Class II and higher products can be sold only after they are certified as conforming to the quality certification mark (CE Mark) of a third-party organization in the EU.

For medical devices not included in the GHS, there is a pricing system called "LPP (liste des produits et prestations)," similar to Japan's Special Designated Treatment Material (STM), which is different from the lumpsum payment (for more on STM in Japan, see Tamura et al. (2019)).

In determining whether or not there is a reason for additional reimbursement as LPP, the criteria are 1) rapid technological innovation, 2) the price is so high that it does not fit in with lumpsum reimbursement, or 3) the number of eligible patients is small and the costs required for lumpsum reimbursement cannot be calculated. Products that do not meet these criteria are not considered as LPP items (Fukuda 2014).

The process of listing a medical device on the LPP after obtaining regulatory approval (CE Mark) involves several government agencies evaluating the product. The main focus is the technical evaluation conducted by the CNEDiMTS (Committee for Evaluation of Medical Devices and Technology), which consists of two aspects: "medical benefit SA evaluation" (two levels: sufficient/insufficient) and "degree of improvement/added value: ASA evaluation" (five levels: I-V, with I being the highest evaluation), which is a relative evaluation. Additional health economic evaluation will be conducted for medical devices that are expected to have a significant impact on medical insurance expenditures, but the number of products to which this applies is currently limited (Chuikyo Data 2015).

There are two types of LPPs: 1) brand name-based listing, in which products are listed by trademark or product name, and 2) generic line, in which products are listed by product type. The brand name listing is for products that are innovative, have a significant impact on healthcare financing, or have a high public health need. Some products are innovative and become generic lines over time, even if they are initially listed by brand name.

1.2.3 Coverage with Evidence Development (CED)

The so-called CED is a system to support the reimbursement listing of new products. As in other European countries, clinical evidence on efficacy is not always required at the time of regulatory

approval[v], and thus there are many cases where a product is not covered by reimbursement even after regulatory approval has been granted, thus preventing patient access to innovative medical devices. To address this situation, the CED program was introduced for medical devices and technologies in 2007 (Martelli 2016).

If the program is applied, patient access to new medical devices will be granted on an interim basis while evidence is collected to determine if reimbursement is to be given. In addition, all funds necessary for evidence collection will be covered by the insurer.

However, because the definition of innovative medical devices was unclear and medical device manufacturers themselves could not apply to the program, only two products were eligible for the program after nearly ten years. In 2015, therefore, the criteria for a product to be innovative were clarified, and the system was revised to allow medical device manufacturers themselves to apply directly to the program.

At present, the following three types of programs exist as CEDs.

1.2.3.1 PHRC (Programme Hospitalier de Recherche Clinique)

The PHRC is a program for breakthrough technologies for which no clinical evidence has been collected. In addition to regular medical fees, the government reimburses medical institutions for clinical research. Usually, the research is conducted at a single medical institution for a period of up to two years. The clinical research is led by the medical institution and, in principle, does not involve companies.

1.2.3.2 PRME (Programme de Recherche Medico-Economique)

PRME is a program for medical technologies and devices that have demonstrated efficacy and safety but lack economic data.

1.2.3.3 Forfait Innovation

This is a clinical study, with a comparison group, of a breakthrough technology for which there is a lack of evidence. The government will pay for the experimental group (new technology), the public health insurance will pay for the control group, and the companies will pay for the infrastructure (protocol development, data analysis). Companies apply for the project, and the government conducts the subject selection.

1.3 United Kingdom

The NHS is characterized by the following: (1) in principle, there is no cost-sharing for medical care; (2) all residents are eligible for benefits; (3) benefit levels are based on clinical need; (4) benefits are comprehensive health services, including prevention, treatment, and rehabilitation; and (5) most costs are covered by taxation and the system is centrally administered. Approximately 80% of the financial resources comes from taxation, and the remaining 20% comes from National Insurance, which is mainly intended to provide income security such as pensions. The National Institute for Health and Care Excellence (NICE) effectively decides benefits for new medical technologies in the NHS. The guidance issued by the NHS includes “Recommended,” “Optimized,”

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v In May 2017, the European Medical Device Regulation (MDR) became effective as a new European medical device regulation to replace the Medical Devices Directive (MDD), requiring more clinical data on efficacy, etc. than in the past (application was scheduled for May 2020, but was postponed by one year due to the new coronavirus infection, and application began in May 2021).

"Therapeutic Use Only," and "Cost-Effective," and is intended to promote the appropriate selection of treatments, drugs, and medical devices through economic evaluations such as "cost-effectiveness." Recommended items must be made available to providers for a certain period of time. On the other hand, "Not Recommended" items are not reimbursed for service costs, with some exceptions, and thus affect the actual coverage of benefits.

1.3.1 Reimbursement for Inpatient Care

Public hospitals are organized as either NHS Trusts, which are directly responsible to the Department of Health, or NHS Foundation Trusts, which are organizationally independent of the NHS.

All public hospitals contract with Clinical Commissioning Groups (CCGs) [vi], which are made up of local clinics, to provide services and are paid according to the volume of services actually provided by the service provider based on Healthcare Resource Groups (HRGs). The DRG (Diagnosis Related Groups) rate includes medical staffing costs, and the HRG rate accounts for about 60% of hospital revenue.

1.3.2 Reimbursement for Medical Devices and Equipment

As a rule, medical devices are included in the lumpsum payment under the HRG. Pricing of medical devices is free, but hospital budgets are controlled by the CCGs. Additional payments may be made for new products that are used in larger quantities or at higher prices, based on the Innovation and Technology Tariff (ITT), etc. (see below).

1.3.3 Evaluation and Promotion Systems to Encourage Innovation

As in Germany and France, the United Kingdom has the following systems for promoting the use of new technologies and building evidence.

1.3.3.1 Commissioning through Evaluation

From among promising technologies for which clinical evidence is lacking, NHS and other public organizations will select target technologies and conduct clinical research for about three years with a maximum of 400 cases (all costs will be funded by NHS). NICE and other organizations will submit a research report on the results.

1.3.3.2 ITT (Innovation and Technology Tariff)

This system provides financial support for technologies that have evidence and are well established as technologies but are not yet sufficiently widespread. From among the technologies and devices applied for, the NHS and other public organizations will select appropriate technologies and devices, the selected technologies being treated as so-called "zero-cost models" for two years. Medical institutions can use the technology/device concerned free of charge, and the NHS pays the cost directly to the supplier.

1.3.3.3 ITP (Innovation Technology Payment)

Financial support will be provided for low-cost, high clinical utility, or highly efficient technologies that result in cost reduction. The selected technologies will be reimbursed separately

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vi CCGs are responsible for planning, procurement, and management of non-primary, secondary, emergency, and maternal and child health care CCGs' decision-making units include local clinics, hospital-based doctors and nurses, and residents. As of 2015, there were 209 CCGs across England.

from DRGs or procured by the government for use in medical institutions. The technologies selected will be reimbursed separately from DRGs as they are used, or procured by the government for use in medical institutions.

1.3.4 Quality Improvement Measures

Since payments based on HRGs are made based solely on the amount of activity related to treatment, two reimbursement measures are also in place to achieve quality improvement (Matsumoto (2015)).

One is the Commissioning for Quality and Innovation (CQUIN), introduced in 2009, which pays for the achievement of quality improvement targets. CQUIN payments are limited to a maximum of 2.5% of the normal fee payment made to hospitals (NHS England, 2016).

The second is the introduction of the Best Practice Tariff, which began in 2010. This is a system that rewards high-quality, cost-effective medical practices. Payments based on the Best Practice Tariff are applied when treatment for specific diseases, such as stroke, cataracts, and hip fractures, is provided according to the path recommended as best practice (Hori, 2016:136).

1.4 United States

There is no public health care coverage system for the entire population. There are two public health care systems: Medicare, which covers the elderly over 65 years old and the disabled, and Medicaid, which covers low-income individuals who meet certain conditions. In 2014, the government began requiring people to purchase health care insurance, and the government has been working to reduce the number of uninsured people by expanding the number of people covered by private insurance and Medicaid. Since 2015, companies with 50 or more employees have been required to offer health insurance to their employees, and most of the uninsured are enrolled in insurance plans through company benefits and other means.

1.4.1 Reimbursement for Inpatient Care

The lumpsum reimbursement system based on DRGs, which was introduced in 1983 and pioneered worldwide, is still the basis of reimbursement for inpatient care in the United States under Medicare. After the introduction of DRGs, as the shift of inpatient care to outpatient facilities and the collaboration with facilities with acute functions progressed, various additions, subtractions, and revisions were introduced, and the overall system is sometimes referred to collectively as the Hospital Inpatient Prospective Payment System (IPPS).

1.4.2 Reimbursement for Medical Devices and Equipment

Reimbursement for medical devices and equipment is generally included in the DRG/PPS (Diagnosis Related Groups/Prospective Payment System). With new products approved by the FDA (Food and Drug Administration), a new DRG code may be assigned as a result of the submission of various types of evidence, but otherwise payment is made under the existing category.

For new products, companies can increase the selling price to healthcare providers even if they are paid under existing categories; the DRG payment amount is reviewed annually based on cost data for the past several years, but it takes time for this price increase to be reflected in the DRG payment amount, and thus the so-called “payment-lag” occurs. To eliminate the lag, medical institutions may receive additional payments through the NTAP (see below).

To obtain a DRG code for a medical device that requires a completely new procedure, it is first necessary to obtain a Current Procedure Terminology (CPT) code, which is managed and copyrighted

by the American Medical Association (AMA) and is assigned to all services that a healthcare provider may provide to a patient. The CPT code must be included in the claim.

Private insurance plans generally provide their own benefits separately from public health insurance plans such as Medicare, and the methods and amounts of such benefits vary widely.

1.4.3 Innovation Evaluation and Promotion System - NTAP (New Technology Add-on Payment)

NTAP is a program that provides additional benefits to DRGs for a certain period of time for new technologies (medical devices and drugs) with clear clinical usefulness, although the existing DRG payment amount is insufficient.

If NTAP is approved based on the company's application, the medical institution will be paid the lesser of the following amounts for the use of such products.

(1) 50% of the difference between the (original) DRG payment and the total medical cost of the device in question

(2) 50% of the cost of such device

For example, if the original DRG is 1,000,000 yen and the total medical cost (one hospitalization) with the new medical device is 1,500,000 yen, and the cost of the medical device is 600,000 yen, then 1) 50% of the difference between 1,500,000 yen and 1,000,000 yen, which is "250,000 yen" and 2) 50% of 600,000 yen, which is "300,000 yen", would in this example result in 250,000 yen being paid to the medical institution as additional benefits under NTAP.

As noted above, the NTAP will end when the cost of new technology (new medical devices) is reflected in the DRG payment, although the DRG payment amount will be reviewed annually based on cost data for the past several years, including the cost of medical devices.[vii]

1.5 Australia

Australia's health care coverage system combines the federal government's Medicare system with private insurance (about 50% of the population is covered by private health insurance). Medicare covers all citizens and provides universal coverage through a tax system. At the same time, private medical insurance and private medical services are widely used in the country to achieve both "universality," "choice," and "amenity" for users. There is no co-payment for hospital and doctor fees in public hospitals with public insurance, but there is a co-payment for patients with private insurance in public hospitals and private hospitals.

1.5.1 Reimbursement for Inpatient Care

In Australia, Diagnosis Related Groups (DRGs) are used for acute inpatient care, and the Australian Refined DRG (ARDRG), the Australian version of DRGs, is used for budget allocation from state governments to public hospitals.

1.5.2 Reimbursement System for Medical Devices

There are two types of medical devices: Those that are included in the Protheses List (PL) and for which a published price is set, and those that are covered by technical fee. PLs can be (1) surgically implanted in a patient for the purpose of either replacing a physical site or adjusting a pathological process, or (2) essential for the implantation of a specific product and disposable. In principle, medical devices for examination purposes and non-implantable medical devices are paid

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vii Whether or not all products approved by the FDA as breakthrough medical devices (breakthrough devices) should be covered by the NTAP is being discussed.

for on a lumpsum basis.

There are two types of PLs: No-gap devices with zero patient cost and gap-permitted devices that require patient out-of-pocket.

The Australian Private Medical Insurance Act requires private medical insurance companies to pay mandatory benefits, along with doctor fees, for certain medical devices used in the course of treatment covered by Medicare benefits in hospitals.

When listed in the PL, the cost of the devices is paid to the medical institution, thus allowing the medical institution to use those devices without financial considerations. For example, pacemakers and ICDs are listed in the PL, but catheters for ablation therapy are not. Also, coronary stents are listed in the PL, but pressure wires are not.

In principle, implantable products are listed in the PL and thus treated as such, but the introduction of pressure wires has been delayed, especially in municipal hospitals, because medical institutions must bear the cost of these products, even though they are considered important for promoting the proper use of coronary stents (Griffin 2015).

2 Differences between the above five foreign countries and the Japanese system, and implications for Japan

2.1 Individual Reimbursement or Lumpsum Payment for Medical Devices/Equipment

First, let us consider whether reimbursement prices are set individually for medical device and equipment, or whether they are reimbursed as part of a lumpsum payment of a single hospitalization, as in DRG. As we have seen, Germany, the UK, and the US have lumpsum reimbursement, while France and Australia have reimbursement prices set for some medical devices and equipment. In Japan, as in France and Australia, some medical devices and materials have their own reimbursement price as Specified Insured Medical devices.

The pros and cons of each system are considered below.

2.1.1 Pros and Cons of Having Reimbursement Prices Set for the Medical Devices and Materials Themselves

The first advantage is that medical institutions do not lose money financially as long as they purchase the product at that price (or lower), and can in principle use the product they need clinically and in the amount they need without worrying about economic aspects (however, limits may be set on the applicable target, number of uses, etc.).

Furthermore, when a manufacturing and marketing approval is obtained for a breakthrough product, a higher reimbursement price may be set than for conventional products. In such cases, it is interpreted that the government has officially recognized the high value of the product, which has advantages for medical device companies, such as making negotiations with medical institutions easier.

On the other hand, if a product among newly approved products represents an improvement in ease of use for the healthcare provider, a smaller product, or a minor improvement in product performance, the new reimbursement price will not necessarily reflect the characteristics of the individual product and may be the same as the reimbursement price for the existing product category. This is one of the disadvantages[viii].

viii In the case of Japan's STM reimbursement system, each price revision is accompanied by a price reduction in relation to prevailing or foreign prices, which is sometimes seen as a disadvantage of the system for companies.

In general, the majority of medical device developments consist of a series of small incremental improvements. If these incremental improvements are not adequately evaluated through reimbursement prices and do not result in increased revenues for companies, then R&D costs will not be fully covered, reducing development incentives for companies. This may delay the emergence of new technological innovations in the medical field and may hinder the improvement of the quality of care.

2.1.2 Pros and Cons of Lumpsum Payment

One advantage of lumpsum payment is that it is relatively easy for payers (insurers) to control medical costs. On the other hand, for medical institutions, costs may exceed reimbursement prices in terms of individual patients, and this may restrain the use of new medical devices and equipment.

For companies, the reimbursement price of the lumpsum payment includes all hospitalization, labor, and drug costs, which leaves room for raising the price of improved products and creates an incentive to actively introduce improved products. This is the reverse of the disadvantage of having reimbursement prices set for the medical devices and materials themselves, as described above.

On the other hand, when the price of an improved product is raised, the cost portion of the lumpsum payment increases for the purchasing medical institution, which puts pressure on profits, making it difficult to actively purchase the improved product even if it is clinically useful.

In order to solve these problems, a reimbursement price surcharge system for a certain period of time, described in the next section, exists in Germany, the UK, and the US, where lumpsum payments are made.

2.2 Reimbursement Add-on Program for a Certain Period of Time

In the lumpsum payment systems in Germany, the UK, and the US using DRGs, etc., the government periodically surveys the costs incurred by medical institutions and reflects them in the amount of the lumpsum payment. However, there is a time lag in this reflection, and when the purchase price of new medical equipment increases, medical institutions suffer financially in the meantime.

The NUB in Germany, ITT in the UK, and NTAP in the US have been introduced to solve the problems of these lumpsum payment systems. Systems similar to these do not exist in France and Australia, where reimbursement prices are given for each medical device and material.

2.3 Clinical Evidence Collection Support System

Many countries have introduced systems to promote the collection of clinical evidence in order to make appropriate decisions on whether or not to provide reimbursement.

Especially in Europe, under the CE Mark, regulatory approval was granted with less clinical data than in Japan and the U.S., and there were many products that were not reimbursed even after obtaining approval.

Therefore, a system has emerged in which the government provides incentives to medical institutions and companies in various ways to promote the collection of clinical evidence.

In a survey of 22 European countries conducted by Federici (2021), seven countries had programs to support the collection of clinical evidence, with varying methods.

The applicants were “companies and medical institutions” in France, the Netherlands, and Switzerland, and “government and public institutions” in Belgium, the United Kingdom, Germany, and Spain.

As for the funding, in most cases, the costs related to the provision of medical care itself were paid by the public health care system, but the operational costs of creating research protocols, data collection, and analysis were in some cases covered by public funds (Belgium, Spain, and the United Kingdom) and in other cases partially or entirely by the system applicant (France, Germany, and Australia).

Among the five countries that have been discussed so far, the Erprobungsstudie system in Germany, the PHRC and the Forfait innovation system in France, and the Commissioning through Evaluation system in the UK are considered to be clinical evidence collection support systems.

Japan's Advanced Medicine (Senshin Iryo) is similar to the European system in some respects, but the applicant is the medical institution, the cost of the medical care itself is borne by the public medical insurance and the patient, and the medical institution bears the operational costs of creating research protocols, collecting data, and analyzing the data.

Another difference between the systems in European countries and Japan is that most of the systems in European countries cover items that have been approved by the regulatory agencies, while in Japan, although Advanced Medicine A covers items that have been approved by regulatory agencies as in Europe[ix], Advanced Medicine B covers items that have not been approved.

In Japan, medical technologies (pharmaceuticals, medical devices, etc.) that have been approved by regulatory agencies are, in almost all cases, reimbursed by National Health Insurance. In particular, the rule for pharmaceuticals is that they must be covered by insurance within two to three months of approval, with the exception of certain items for preventive purposes. In the case of medical devices, there are some approved products that are not listed on the insurance list, but even so, those that are not reimbursed are the exception. Therefore, it can be said that advanced medicine B, which is not regulatorily approved, is positioned somewhat differently from non-approved items in European countries.

2.4 Implications for Japan

We have reviewed medical device reimbursement systems in other countries and examined their characteristics. Let us now consider the implications for the Japanese system in terms of two points that were identified as differences from the Japanese system: "reimbursement evaluation of product improvements" and "handling of cases in which clinical data are insufficient."

2.4.1 Reimbursement Evaluation of Product Improvements

As discussed above, "improvement" is key to medical device product development. While there are some cases where a completely different and revolutionary product is created (Goto, 2018), in most cases, minor incremental improvements improve the quality of the product, and thereby the outcomes.

In order to continuously encourage such improvements, it is extremely important to evaluate them. To address this issue, Japan's reimbursement system established an "additional improvement fee" in 2008.

However, the number of improvement additions applied for peaked in 2012-2014 and has been declining (Table 2).

ix Unapproved *in vitro* diagnostic products are also included in Advanced Medicine A.

Table 2: Number of Improvement Additions

Period	Number of improvement additions
2008-2010	6
2010-2012	8
2012-2014	32
2014-2016	14
2016-2018	7
2018-2021	10
Total	67

While the possibility that the actual number of product introductions corresponding to improvement additions may have fluctuated cannot be ruled out, as Tamura et al. (2019) point out, it is also possible that there has been a change in the administrative authorities' approach to the evaluation of improvements. Starting in 2018, a "time-limited improvement addition" (B3) was created, but this addition was granted in only one case, and it is difficult to say that it is functioning adequately at present.

In contrast, in other countries, there is an aspect in which consideration is given to the improvement of medical devices. In other words, in order to make it easier for medical institutions to purchase improved medical equipment when the purchase price increases, a system is established whereby the reimbursement price is increased until the amount of the lumpsum payment increases, including the increased cost of the medical device.

The medical device industry has been requesting revisions to time-limited improvements (B3), and including such improvements, and further incentives for medical device companies to make improvements, would be an important element in terms of capturing advances in medical technology and improving the quality of medical care.

2.4.2 Lack of clinical data

In other countries, especially in Europe, the hurdles for regulatory approval have been relatively low in the past, and various systems have been established to accumulate the clinical data necessary to make decisions on reimbursement.

In Japan, as mentioned above, there is also a system of Advanced Medicine, but its positioning is somewhat different from that of Europe. In terms of the accumulation of clinical data after approval, Japan established a "challenge application" system in 2018, under which evidence is collected and submitted after the product is placed on the reimbursement list and reevaluated. This means that if all the characteristics of a medical device cannot be fully evaluated at the time of reimbursement coverage, even if the device is insured at an undervalued reimbursement price, for the time being, there is a pathway for it to be appropriately evaluated later on.

In Japan, "device lag"[x] became a social problem in the late 2000s, and the need for expedited regulatory approval was called for. It is good news for the medical community and patients that medical devices embodying new technologies are approved more quickly and that an environment is created for their widespread use. On the other hand, it is also true that if regulatory approval is accelerated, it will be difficult to prepare and evaluate sufficient data to accurately demonstrate the value of the technology. Challenge applications are effective in reconciling these two contradictory situations. The establishment of such a system is highly significant because it is sometimes more difficult to secure

x Device lag refers to the fact that medical devices that can be used overseas cannot be used in Japan.

clinical data for some medical devices than in the past due to the limitation of the indications for which the device is recommended and other factors. Since the establishment of this system, five challenge applications have already been approved, and awareness of the need for this system is growing.

The compatibility between rapid introduction of technology into society and appropriate evaluation with sufficient data is a common challenge, regardless of the insurance system's treatment, whether it be lumpsum or individual evaluation. This challenge application system, which was only for STM when it was first introduced, but was also applied to Non-STM (technical fees) from 2022.

Finally, in Europe and the US, as in Japan, there is a growing demand for value-based pricing in response to rising healthcare costs (Sorenson et al. (2013)). In line with such trends, for example, in the EU countries, it is reported that the number of cases in which Patient-Reported Outcome Measures (PROMs) are added to the approval review process, in addition to the conventional efficacy and safety measures, is increasing.[xi] (Miklós et al. (2019). This is true not only in EU countries, but also in the US, where studies using PROMs increased by more than 500% between 2009 and 2015 (ibid.) The increased use of PROMs in EU countries has been attributed to public procurement guidelines issued in 2014 (Directive 2014/24/EU). In the procurement of medical devices, more emphasis is being placed on aspects such as quality, life cycle costs, cost-effectiveness, and social benefits, in addition to the traditional price advantage. In Japan, it is expected that the trend toward evaluating medical devices based on the value they bring will become even stronger, and a more multifaceted value evaluation method utilizing patient-reported outcomes, etc., must be established.

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