HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's-eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

The Ministry of Health, Labour and Welfare (the MHLW) is responsible for the public healthcare system in Japan as a whole, overseeing delivery, formulating policies and regulating healthcare systems and insurance costs. Under this system, 47 prefectural governments implement regional public healthcare plans and manage budget and insurance costs.

Under the universal healthcare insurance system designed by the Japanese Government, all residents in Japan are covered by public health insurance. This system allows residents in Japan to receive high-quality medical treatment at relatively low cost from healthcare providers and facilities of their choice.

Japan primarily offers three different categories of public health insurance programmes: (1) National Health Insurance (*kokumin kenko hoken* – NHI); (2) Employees' Health Insurance (*hiyosha hoken* – EHI); and (3) the Late-Stage Medical Care System for the Elderly (*koki koreisha iryo seido*). Within these categories, NHI and EHI are the most common programmes. EHI covers employees working in the public sector or employed by private entities. The Late-Stage Medical Care System for the Elderly covers those residents aged 75 or older, or 65–74 who are certified as having a specific disability by the applicable wide-area union. NHI covers the remaining residents who are not categorised under EHI or the Late-Stage Medical Care System for the Elderly, including individuals who run their own businesses, such as the self-employed, as well as the unemployed.

Under the universal healthcare insurance system, residents are free to choose their healthcare providers and facilities. In other words, the type of healthcare insurance programme or the health insurers a resident has enrolled in (eg, NHI, EHI, Late-Stage Medical Care System for the Elderly) does not restrict the resident's choice of healthcare providers.

Private companies in Japan offer optional health insurance programmes. Enrolment is not mandatory, allowing residents to choose freely whether to participate. Since treatment outside of public health insurance schemes are fully self-paid, private health insurance programmes offered by private insurance companies are available to cover the patient's co-payments and other medical care costs not covered by public health insurance programmes.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

Japan has various laws that govern its universal healthcare insurance system, depending on the type of insured individual. These include: (1) the Health Insurance Act (*kenko hoken ho*) for

employees in the private sector; (2) the Mutual Aid Association Act for National Public Officers (*kokka komuin kyosai kumiai ho*) for employees in the public sector; (3) the Act on Assurance of Medical Care for Elderly People (*koreisha no iryo no kakuho ni kansuru horitsu*); and (4) the National Health Insurance Act (*kokumin kenko hoken ho*) for the self-employed and unemployed.

Furthermore, there are regulations that determine which medical services and therapeutic products will be covered by the universal healthcare insurance system. These regulations include: (1) the Rules for Health Insurance-covered Medical Facilities and Medical Practitioners (*ryotan kisoku*) and (2) the Rules for Health Insurance-covered Dispensing Pharmacies and Pharmacists (*yakutan kisoku*).

The MHLW has the authority to decide the medical fee points (*shinryo hoshu tensu*), the uniform fee schedule specifying the payments that the universal healthcare insurance system will make to each insurance-covered healthcare provider for delivering each covered medical service after consulting with the Central Social Insurance Medical Council (*chuo shakai hoken iryo kyogikai* – 'Chuikyo'). The Minister of Health, Labour and Welfare (the Minister) revises the uniform fee schedule every two years.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

As forementioned, the MHLW is responsible for the public healthcare system in Japan as a whole, overseeing delivery, formulating policies, and regulating healthcare systems and insurance costs.

Regarding the implementation, an entity known as Health Insurance Claims Review & Reimbursement Services (*shakai hoken shinryo hoshu shiharai kikin* – HICRRS) plays a crucial role. HICRRS is responsible for reviewing health insurance claims to ensure accuracy and compliance with regulations, as well as managing the reimbursement process for healthcare providers. To explain the process, after providing medical services, the healthcare provider submits a health insurance claim to HICRRS to receive reimbursement for the portion of medical fees not covered by the patient. HICRRS reviews the claim to ensure its accuracy and compliance with regulations. Once the claim is validated, HICRRS requests the appropriate payment amount from the insurer. The insurer then disburses the payment to the healthcare provider through HICRRS, ensuring that the provider is compensated for the services rendered. By overseeing these functions, HICRRS helps maintain the integrity and efficiency of the universal healthcare insurance system, ensuring that providers are fairly compensated for their services and that patients receive the benefits they are entitled to under the system.

The role of courts and the judicial system in the universal healthcare insurance system is limited. However, if disputes arise among parties involved in the reimbursement process, such as disagreements over the validity of a claim or the amount reimbursed, the matter may be escalated to the court system.

4. Has there been a change with healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

The Japanese government spent an additional JPY77tn to implement measures against the Covid-19 pandemic. This included healthcare financing and reimbursement, as well as other initiatives such as expanding the scope of permitted telemedicine. However, the universal

healthcare insurance system itself remained unchanged before and after the Covid-19 pandemic. During the pandemic, the MHLW implemented expedited reviews for the marketing approval and drug price standards of drugs and vaccines relevant to Covid-19.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

Under the Japanese universal healthcare insurance system, every resident in Japan, regardless of nationality, is required to enrol in a public health insurance programme unless the resident is protected under other governmental programmes (eg, public assistance programme). This mandate ensures that all residents have access to necessary medical services and helps to distribute the cost of healthcare across the population. Anyone, including non-residents, may voluntarily enrol in a private health insurance programme, in addition to the public health insurance programme, to supplement for any areas they consider are insufficiently covered under the public healthcare insurance system. If a resident receives emergency medical services outside of Japan, a portion of the medical expenses may be covered if those services are included under Japanese public health insurance. If a non-resident receives medical services in Japan, the non-resident will bear the full cost of the medical expenses unless they are enrolled in a private health insurance programme.

For medical facilities and pharmacies, it is economically advantageous to be designated as insurance-covered facilities (*hoken iryo kikan* and *hoken yakkyoku*). Since every resident in Japan is enrolled in a health insurance programme, they are unlikely to choose facilities that are not designated as insurance-covered facilities, as patients would have to bear the full cost of the services they receive.

In order for medical facilities and pharmacies to participate in the Japanese public health insurance system, they must be designated as insurance-covered facilities in accordance with the Health Insurance Act. After the establisher of a medical facility or pharmacy files an application with the applicable Regional Bureau of Health and Welfare (the Regional Bureau), the Regional Bureau designates the medical facility or pharmacy as insurance-covered unless such participant, or its establisher, violates the Health Insurance Act or other relevant laws. Additionally, physicians, dentists and pharmacists offering services at insurance-covered facilities must apply for and be registered by the Minister as providers of health insurance treatment (*hoken'i* for physicians and dentists, and *hoken yakuzaishi* for pharmacists).

Only prescription drugs listed under the drug price standards determined by the Minister are eligible for coverage by public health insurance. The drug price standards set the prices for prescription drugs provided by insurance-covered medical facilities and pharmacies, which are reimbursed by public insurance. Therefore, as soon as pharmaceutical companies obtain marketing authorisation for their developed prescription drugs, they apply for inclusion in the drug price standards. Pharmaceutical companies may determine the prices of other pharmaceuticals that are not listed in the drug price standards.

For medical devices, companies that market such devices should apply for inclusion in universal healthcare insurance coverage after obtaining or performing the necessary marketing authorisation procedures.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

In 2021, total medical benefit costs in Japan amounted to JPY42.1tn. These costs were funded by three main sources: premiums (53 per cent); subsidies funded by central, prefectural and municipal governments (32.5 per cent); and out-of-pocket expenses paid by the insured (14.5 per cent).

Each public health insurance programme determines the amount of premiums to be paid by each household. Each municipality determines the premiums for the national health insurance programme based primarily on each household's income from the previous year and a fixed amount per household member. Factors such as the number of insured persons, age composition, and the amount of medical expenses to be covered by insurance also influence this determination. For EHI, the health insurance associations and societies determine the premiums based on the employee's salary. These premiums are generally shared equally between the insured employee and the employer. The premiums for the Late-Stage Medical Care System for the Elderly are determined in a manner similar to those for the national health insurance programme. However, these premiums are assessed on an individual basis rather than per household. The MHLW has recently announced that, as a future policy for determining premiums, it is important for all citizens, regardless of age, to support the healthcare insurance system fairly according to their ability to pay.

Japan employs a co-payment system where patients are required to pay a percentage of their medical costs out-of-pocket, while the remaining costs are covered by public health insurance. These co-payment rates can be generally categorised into three age groups: (1) 30 per cent for patients aged six to 69; (2) 20 per cent for patients younger than six or 70–74; and (3) 10 per cent for patients aged 75 and older, and for those aged 65–74 who are certified as having a specific disability by the applicable wide-area union. Furthermore, to prevent excessive financial burden on individuals, Japan has implemented the High-Cost Medical Expense Benefit (*kogaku ryoyohi seido*), which sets a monthly cap on the out-of-pocket expenses an individual must pay. Any amount paid over this cap will be reimbursed to the patient. The cap is determined based on the insured's salary.

7. How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?

The universal healthcare insurance system covers the same sets of services, pharmaceuticals (including orphan drugs), and medical devices, with specifics defined by laws and regulations (eg, the Rules for Health Insurance-covered Medical Facilities and Medical Practitioners and the Rules for Health Insurance-covered Dispensing Pharmacies and Pharmacists). The Minister determines the scope and prices of medical services, phamaceuticals and medical devices that are covered by the public health insurance system based on discussions by Chuikyo. Chuikyo is a key advisory body within the MHLW, primarily responsible for reviewing and making recommendations on matters related to the public health insurance system. Its members include healthcare providers, insurers, public interest representatives, and other experts.

The Japanese healthcare system generally prohibits mixed billing (*kongo shinryo*), which refers to combining treatments covered by public health insurance with those that are not covered by insurance. Therefore, a patient cannot receive both insured and uninsured medical services

simultaneously. This rule is in place to prevent an increase in patients' out-of-pocket expenses and to maintain the fairness of the healthcare system.

However, there are certain exceptions where mixed treatments are allowed under specific conditions. For example, advanced medical treatments (*senshin iryo*) may be combined with insured treatments. In such cases, the advanced medical care portion is paid out-of-pocket by the patient or, if applicable, private health insurance, while the rest of the treatment is covered by public health insurance.

In principle, telemedicine appointments are used in conjunction with in-person visits for providing continuous treatment. Since the information that physicians can obtain through telemedicine appointments is generally less comprehensive compared to in-person visits, telemedicine services are more limited in scope and cost less than those for in-person visits.

The universal healthcare insurance system does not generally cover pharmaceuticals for off-label use unless approved by the MHLW.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

The services provided by hospitals in both inpatient (stationary) and outpatient (ambulatory) settings are financed and reimbursed under the same healthcare system, meaning that the same co-payment rates apply to both settings.

The base medical fees for inpatient and outpatient settings differ, but the same fees apply for other treatment services. In an inpatient setting, hospital charges typically account for more than 50 per cent of the total medical fees. Consequently, many private health insurance providers commonly offer coverage to supplement hospital charges.

Although the premiums of the public healthcare insurance system are largely funded by the younger population, the elderly are likely to use inpatient services more frequently. With the younger population in Japan declining, the country may face a shortage of government funds in the future. Japan is confronting the challenge of developing sustainable solutions to address this impending financial issue.

9. How are the prices of such services determined? How is economic efficiency controlled?

The Minister determines medical fee points (*shinsatsu hoshu*) for each medical service, pharmaceutical and medical device based on discussions by Chuikyo. A patient will pay the total points for services that the patient receives. Each medical fee point is equivalent to JPY10, and the prices of medical services offered by health insurance-covered medical facilities and pharmacies are calculated based on this point system. The total cost will be covered primarily by the universal healthcare insurance system, with the remainder paid out-of-pocket by the patient.

For medical devices, prices may be assessed as part of technical fees in medical services. However, if medical devices are classified as special treatment materials (STM), they will be reimbursed separately from the technical fees at the prices specified by their functional

category. These prices, along with the prices for services, will be summed up to calculate the total medical fees.

Medical fees are reevaluated every two years (every year for drug prices). The MHLW sets the basic policy, and Chuikyo discusses and reviews the proposals. Based on these discussions, the MHLW drafts specific revision proposals, which are then made public for comments. After considering public feedback, the MHLW finalises and announces the revised medical fees, which are typically implemented from the following year. This process aims to enhance healthcare quality and manage costs effectively.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

Healthcare services provided by private practitioners are financed and reimbursed in the same manner as for hospitals in the ambulatory/outpatient setting.

11. How are the prices of such services determined? How is economic efficiency controlled?

Again, prices of such services are set and their economic efficiency is controlled in the same manner as for hospitals in the ambulatory/outpatient setting.

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

To begin with, the majority of medical services in Japan are provided as insurance-covered treatment within the framework of the universal healthcare insurance system. Most prescription drugs and medical devices used in medical services are financed and reimbursed through the universal healthcare insurance system, unless the Minister excludes them from the list of covered items (eg, contraceptives and vaccines). The use of these items in medical services is incorporated into the medical fees (*shinryo hoshu*).

The MHLW determines which drugs will be reimbursed and sets the drug prices for reimbursement under the universal healthcare insurance system. The prices of drugs eligible for reimbursement (*yakka*) are listed under the drug price standards (*yakka kijun*) and are reevaluated in principle every year. The drug price standards also include orphan drugs. Insurance-covered physicians, dentists and pharmacists are in principle not allowed to use pharmaceuticals other than those listed in the drug price standards. The prices of drugs used in medical services will be added on top of the medical fees. Furthermore, early-access products that are approved abroad but not yet approved in Japan may also be covered by the universal healthcare insurance system if determined by the MHLW.

The MHLW also sets the prices for the use of medical devices in medical services for reimbursement. As a general rule, the use of medical devices is considered part of medical services, and the cost of these devices is included in the medical fees (*gijutsu ryo*; Technical Fees). In such cases, no separate fees are charged for the use of the medical devices themselves (As mentioned above, if medical devices are classified as STM, they will be reimbursed

separately from the Technical Fees, in a manner similar to drugs, at the prices specified by their functional category.).

Since the use of medical devices in medical services can vary depending on the device, the types of reimbursement for medical devices are broadly categorised into three groups:

1. for medical devices that are used often and are difficult to price separately from Technical Fees (eg, sutures and intravenous blood collection needles), the cost is generally included and assessed as part of the Technical Fees;
2. for medical devices that are inherently tied to specific Technical Fees (eg, laparoscope ports and electroencephalographs), the cost is included and assessed as part of the specific Technical Fees; and
3. for medical devices that are inherently tied to specific Technical Fees but have limited use (eg, ultrasonic coagulation and cutting devices), or medical devices that are loaned out by medical facilities (eg, oxygen cylinders for home use), the cost is assessed as an addition to the specific Technical Fees.

Once the prices are determined, most of the costs will be covered by the universal healthcare insurance system, with the remaining expenses paid out-of-pocket by the patient. Additionally, the patient may choose to obtain private health insurance to cover the remaining costs.

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

In Japan, manufacturers are not permitted to independently set the prices of pharmaceuticals or medical devices that are covered by the universal healthcare insurance system. Instead, the prices are regulated and determined by the MHLW based on discussions by Chuikyo, ensuring that prices are fair and sustainable while maintaining access to essential medical treatment for all residents. This system aims to balance the interests of patients, healthcare providers and manufacturers, promoting both innovation and affordability in the healthcare sector.

Chuikyo is a key advisory body within the MHLW, primarily responsible for reviewing and making recommendations on matters related to the universal healthcare insurance system. It comprises representatives from payers (eg, insurers, patients, and labour unions), healthcare providers (eg, physicians and pharmacists) and neutral public interest representatives (eg, academics). Members of Chuikyo engage in discussions to determine appropriate pricing from their respective standpoints.

The MHLW determines the prices of pharmaceuticals for reimbursement through the similar efficacy comparison method (*ruiji yakko hikaku hoshiki*) or cost-based method (*genka keisan hoshiki*). In principle, the unit price of a new drug is calculated using the similar efficacy comparison method. This method involves selecting a drug from the existing drug price standards that is most similar to the new drug in terms of efficacy. The daily drug price of this comparison drug is then used to determine the price of the new drug. The cost-based method is applied in cases where a new drug has no comparable drugs. This method takes into account the product's manufacturing costs, as well as sales and general administrative expenses, based on various statistics. This method is used as an exception to the similar efficacy comparison method.

Depending on innovativeness, usefulness, marketability and paediatric considerations, an additional price increment may apply. Furthermore, if the determined price significantly differs from foreign prices, adjustments will be made. Since insurance-covered drug prices are based

on the actual transaction prices between medical facilities and pharmaceutical companies, they are subject to revision based on a survey of the actual market transaction prices.

The MHLW also establishes the reimbursement prices for the use of medical devices in medical services. For devices reimbursed in the Technical Fees, the prices are determined similarly to the pricing of medical services. The prices for medical devices classified as special treatment materials (STM) are determined in a manner similar to the pricing of drugs.

Pharmaceutical and medical device companies negotiate with medical wholesalers and distributors, who may in turn negotiate with medical facilities, to determine prices based on those set by the MHLW. These companies are also permitted to offer rebates in compliance with laws, guidelines and industry fair competition codes. The companies' profits are derived from the differences between the negotiated prices and the MHLW-determined prices. Therefore, the prices determined by the MHLW play a key role in the landscape of developing pharmaceuticals and medical devices.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

There are no significant litigation topics or landmark cases concerning healthcare financing or reimbursement in Japan. However, there have been court cases in the past related to the prohibition of mixed billing. As technology continues to advance, there may be an increase in cases related to mixed billing in the future.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes, or trends for healthcare financing and reimbursement and briefly indicate how these may foreseeably affect the medical sector in the near future.

With economic growth slowing, anticipated demographic changes, and a rapid rise in social security costs, including medical expenses, the financial situation is becoming critical, raising concerns about the sustainability of the healthcare system.

The MHLW issued a report titled *Health Care 2035* (*hoken iryo 2035*), highlighting the factors that will impact Japan's medical insurance system in the future. These factors include the effects of a declining birthrate and an aging population, significant changes in the structure of diseases (such as the chronicity and complexity of lifestyle-related diseases and multi-disease conditions), widening regional disparities, relative poverty, increasing generational gaps, the rise in single-person households, and evolving medical needs driven by technological innovation. In particular, the declining birthrate and ageing population have a significant impact on the healthcare system. As the population ages, the severity of diseases progresses, and the nature of medical demand changes, leading to a predicted increase in medical expenditure. Consequently, the report proposes establishing a financial support system to supplement public insurance, reviewing the burden to secure financial resources, and transferring authority to address regional differences in each prefecture.