PEER REVIEWED

Pricing Pharmaceuticals in Japan

Development and pricing strategies to maximise the opportunity in a mature market

Knowing the System:
The NHI System in a Nutshell

In Japan, all citizens are covered under public health insurance. This universal insurance system is called the National Health Insurance, or the NHI System. It is important to understand how this system works, what are the key ideas behind this policy, how the resources flow through it, and who are the stakeholders and decision-makers in order to understand the pricing of pharmaceuticals in Japan and its dynamics. The purpose of this article is not to discuss the overall structure and the details of the NHI System, but instead to summarise the key aspects of it that are relevant to pharmaceutical pricing and market entry strategies.

The spirit of the NHI System is universal healthcare, a system that allows all citizens in Japan to be covered by one of the available public healthcare plans and allows access to any necessary medical resource under any condition. The controlling authority of the NHI System is the Ministry of Health, Labor and Welfare, or the MHLW, one of the eleven highest executive branches in the Japanese government, and on MHLW's website, it describes the system by the following four key features[1].

A. The System provides coverage to every Japanese citizen via public health insurance.

B. The insured has free access to any medical institution of their choice.

C. The insured has access to high level medical treatment at a low cost.

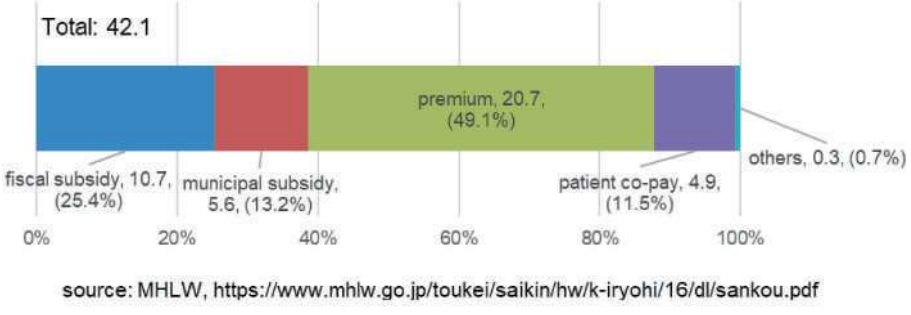
D. The System is structured as a social insurance system, partially supported by public funding in order to maintain universal coverage.

While A is quite self-explanatory, B means that the insured, which is essentially anybody who has citizenship in Japan, can choose any doctor's office they want to visit, and are technically able to go directly to any large hospital to treat their sore throat.

C suggests that everyone can receive high-level medical service, including magnetic resonance imaging or expensive oncology therapies, at a relatively low cost. Note that all the medical treatments approved by the MHLW (with the exception of "lifestyle treatments" e.g. alopecia drugs) will be automatically covered by the NHI System. It will be subject to reimbursement at an equal level across all the approved treatments. This is unique compared with other parts of the world where in some countries the level of reimbursement by the payer may change across different drugs based on the clinical need, level of innovativeness, or for any other reason. The different levels of reimbursement essentially work as an indirect control of the prescription choice. In other words, because of the 'equal-level reimbursement among all drugs' policy adopted by the NHI System, Japanese physicians are relatively free from being restricted by economic incentives at the patient level upon making their choices of treatment.

D implies that while the NHI System is supposed to operate on its inherent finances (i.e. premiums plus copay should pay off all the medical expenses), it is in fact not self-sustaining and depends on external tax-payer money in order to maintain the universal nature of the insurance coverage. Figure 1 describes the source of funding for the NHI System, which points out that about 40% of the cost of healthcare service depends on such public money infusion. Patient copay is a fixed rate of 30% of any medical cost in Japan, but there are various subsidies available to reduce the copay burden, which is why the share of cost is smaller than 30%. Patient copay plays a crucial role in generating the price elasticity of demand for medical services, influencing a patient's decision whether to actually make a visit or not. We will discuss this in detail later.

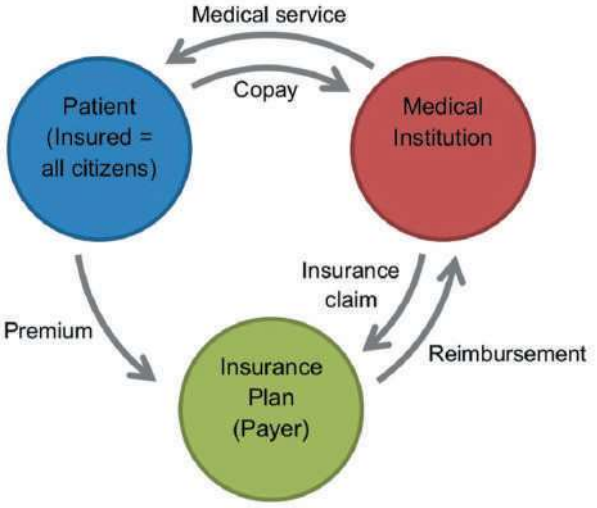
The fiscal subsidy of 10.7 trillion yen to the NHI System is a significant social welfare cost item within the national budget of 96.7 trillion yen (FY 2016), which the Ministry of Finance (MOF) is responsible for managing, and thus there is a natural conflict between the two Ministries. In other words, because of this dependency on subsidies from the public treasury, the NHI System is directly exposed to pressure by the MOF to tighten the budget. The government's target is to run a primary balance surplus by fiscal year 2025, given the current astronomical level of its national debt.



source: MHLW, https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/16/dl/sankou.pdf

Fig. 1, Source of National Health Expenditure (Apr 2016 to Mar 2017, in trillion yen)

Structure and the flow of resources in the NHI System



Source: MHLW, https://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken01/dl/01_eng.pdf

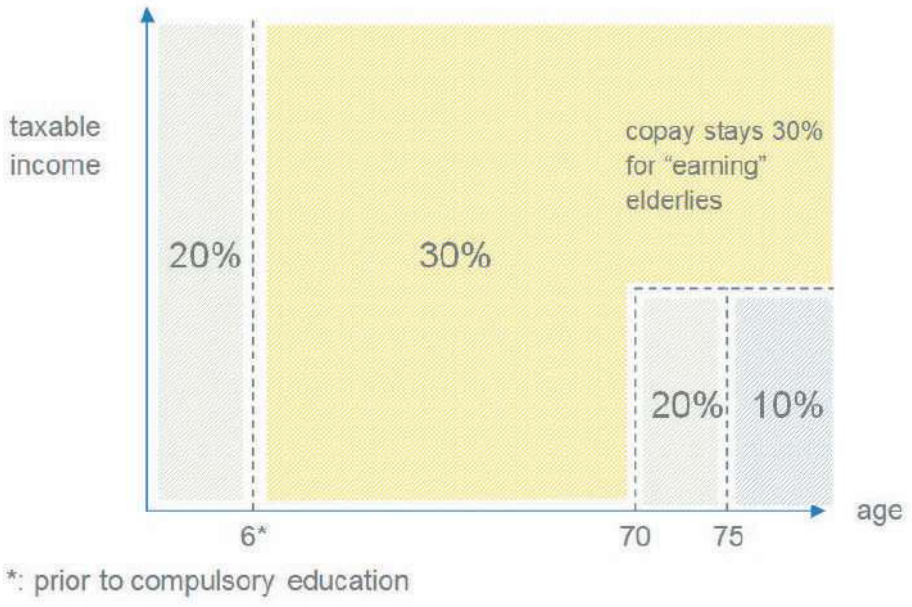
Fig. 2, Schematic of the resource flow in the NHI System

Fig. 2 articulates how the resources flow through the players in the NHI System. As a universal social insurance, all citizens in Japan are covered by one of the insurance plans. There are five types of plans in Japan. Employees of mid- to large-size corporations and their dependents will participate in an employees' insurance plan which is provided by their employers, while those with smaller corporations are covered by a single payer union called Japan Health Insurance Association (Kyoukai Kenpo). Public employees join the Mutual Aid Association (Kyousai Kumiai). There is another plan that is prepared for those above the age of 75 (Late-stage Elderly Policy; Kouki Koureisha Seido). All other citizens, including self-employed and farmers, will participate in a local insurance plan operated by local governments. The participants will pay a premium to their plan and its amount is based on which plan they participate in and the level of the participant's taxable income. Different plans have different financial fundamentals and may require different levels of resource inputs. In order to close this gap and to avoid this difference reflected by various premium payments across different plans, the Japanese government subsidises those financially weak plans, the amount of which is described in Fig.1 as the government and municipal subsidy.

In terms of operating bodies of the insurance plans, the NHI System is not necessarily a "single payer". However, it is important to understand that the payers in Japan neither have the authority to control the reimbursement of the medical services, provided by the institutions, nor can they determine the price of the services. However, they can send a representative to the pricing committee. The only decision that the payers can make is the amount of premium charged to the insurer (particularly in the case of employees' insurance plans). As such, payers in Japan are in a relatively weak position in determining how the medical services should be provided and in balancing out the costs and benefits of the provisions in order to maintain its financial health. This allows us to collectively consider the payers as indifferent and they are effectively behaving as a "single payer".

The choice of medical services provided to the patients is under the sole discretion of the physicians in the medical institutions. The spirit of being able to provide "any medical treatment" to anybody is strongly reflected in this powerful authority given to the physicians. However, the only restriction in terms of the treatment choices, particularly in drug prescription, is that it will have to be within the conditions of the MHLW, described on the label. Otherwise, payers can reject the insurance claim. Payers can decide whether the claimed treatment is within the description of the label and influence the physicians' choice by not reimbursing it. When this happens, the medical institutions have to cover the cost and it will not be passed over to the patients other than the copay, since the decision was made by the authority of the physician.

When the insured receives medical service, they will have to pay a fixed percentage of copay to the institution. It is not the case that the insured will have to first pay the total amount and then claim reimbursement from their insurers. The institution will do that



for them. This benefit in kind allows easy access to medical services without cumbersome paperwork. On the other hand, the copay percentage for most of them is 30% of the entire medical cost, causing the price elasticity of demand as we discussed earlier (percentage of copay depends on the age and the taxable income of the insured; see Fig. 3). We can consider this copay as a prevention against moral hazard, i.e. it prevents the insured from receiving unnecessary medical services. However, this particularly limits the patient's access to innovative drugs that are usually quite expensive. Therefore, the central and local governments prepare various types of subsidies in order to ensure this access to medicine. For example, patients with hepatitis C can apply for subsidisation for most of the treatments, which will make them available for only a small fixed cost of about USD 100~200 per month. This is believed to have contributed to the rapid uptake of the oral antivirals, such as Harvoni, in Japan. In order to develop a solid product launch strategy in Japan, companies must study these subsidies available for patients and engage in lobbying activities to prepare a new policy that ensures better access to new, innovative products.

As discussed, the NHI System is structure-wise prioritising patient access and physician authority over maintaining actuarial balance. This at least partially explains why the Japanese market is so attractive to the healthcare industry.

NHI Price: A List Price Which Benchmarks the Copay and Reimbursement

While each person may need to pay different levels of copay, the percentage of reimbursement is equal across all the approved treatments for a single person.

Any medical service from drugs, medical devices, use of diagnostics, procedures, operations, visits and hospitalisations are covered by the NHI System and available at the same copay percentage. In order for these services to be covered, they need to be included in a list called the Medical Fee Point Schedule. The MFPS is a list of services reimbursable by the NHI System, associated with the "Points" allocated to each item. These Points are essentially the price (actually, the Points are 1/10 of the Japanese yen value. This Point system was originally designed in such a way that the point/value ratio can be changed if necessary, which has not happened since its establishment in 1958) of the services, which is called the NHI Price. Table 1 includes selected items of medical services that are included in the MFPS. For example, if a patient with a 30% copay visits a doctor's office for the first time, before she leaves, she will have to show the certificate of her coverage plan and pay 30% x 282 points x 10 yen = 846 yen to the doctor's office as her copay for the first visit fee. Note that the consumption tax is exempt for this copay. At the end of each month, the doctor's office will make the claim to the plan for the rest of the cost, which is 70% x 282 points x 10 yen = 1,974 yen, and the plan will reimburse the doctor's office. That is how the whole system works.

For drugs, there is a separate list under this MFPS which is called the NHI Drug Price Standard or the NHI Price List. The NHI DPS works in exactly the same way as the MFPS; however, the key difference here is the timing of a new item to be added to the lists. In particular, drugs that are approved by the regulatory authorities (PMDA) will have to go through the NHI pricing process upon the request of the applicant (manufacturer) and will be on the NHI DPS no later than 90 days after the application. In essence, all the approved drugs in Japan will be granted the NHI Price within three months of approval and will become ready to launch. Prices of the drugs granted by the authorities are generally non-negotiable and the authorities will determine the price of each drug by its sole discretion. However, there are a few recent cases where the applicant refused the granted NHI Price and delayed the launch of the new drug in the attempt to negotiate the price. In the next issue, we will discuss the process of drug pricing in Japan in more detail.

Code	Item	Points (1 point = 10 JPY)
A000	First visit fee (fee for the first time you visit any institution)	282
A301 1A	ICU management fee 1 (per day, until seven days)	13,650
K082 1	Artificial joint replacement, knee	37,690
117	Implantable cardioverter defibrillator, type V	JPY* 3,040,000

*: in case of materials (including medical devices) the yen value is directly listed

Table 1. Examples of services listed in the MFPS as of April 2018

REFERENCES

1. https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/iryouhoken01/index.html

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