Pricing and reimbursement in Japan: multiple modes of entry in a fragmented market

With its high level of healthcare expenditure and a willingness to invest in innovative medical technologies, Japan represents a potentially lucrative market for medtech companies. In this article, consultants* at GfK Bridgehead aim to demystify Japan's notoriously complex regulatory and reimbursement systems and provide case studies of how to access the world's second largest medical device market

Japan's healthcare system stands apart from other emerging Asian markets. With annual expenditures of $2,817 per capita in 2008, over ten times higher than China's annual expenditure of $265 per capita, Japan is willing to spend more to access innovative devices and diagnostics; this is evidenced by the size of its market and the high adoption rates of many innovative products. Valued at $1bn in 2009, Japan is the second largest medical device market in the world and imports almost 40% of its products from the US. Despite the heavy demand for healthcare products, however, entering the Japanese medical device market poses considerable challenge for companies due to the exceptionally complex and slow regulatory and reimbursement systems, compounded with in-country market authorisation requirements and, often, the added hurdle of language and cultural barriers.

Japan operates under a fragmented universal healthcare system that is both government- and employer-sponsored, and coverage is determined by an individual's age and employment status (Table 1).

Regardless of the carrier, Japanese citizens receive coverage according to a standard national benefits package. Packages cover a broad range of services including in- and outpatient care, dental care, and some pharmaceuticals, though programmes cover little in the way of preventive care. In addition, limited options exist for better quality care and many novel or advanced treatment options are unavailable in Japan. Plans are financed primarily by the national government, private employers, and individuals by coinsurance payments; individuals often purchase private supplementary insurance to cover high out-of-pocket expenses resulting from standard 30% coinsurance rates.

All hospitals and physician offices are not-for-profit by law, although 80% of hospitals and 94% of physician offices are privately operated. General practice is an evolving field and specialists currently operate outpatient clinics. In addition, specialists may claim any subspecialty without additional accreditation. Patients have easy access to medical care and an average 13.9 physician visits per year. Fee-for-service reimbursement incentivises physicians to increase the volume of patients they treat and two-thirds of patients spend less than 10 minutes with their physician.

Prior to recent changes by the Ministry of Health, Labor and Welfare (MHLW), the Japanese approval process was quipped the "drug and device lag." This lag was a product of complex manufacturing and approval processes that required Japan-specific documentation and clinical trials. In over 96% of devices marketed in the US, EU and Japan, Japan was the last country in which the product was introduced. These processes constrained treatment protocols and individuals often only had access to second or third generation medical devices. These issues prompted the MHLW to pass laws in 2004-2005 addressing barriers to entry.

As of April 2005, the Japanese Pharmaceutical Affairs Law (JPAL) requires that all medical devices and pharmaceuticals released in the Japanese market be under the control of

Table 1: Healthcare payers in Japan

Payer	Covered individual	No. lives covered	No. insurers	Annual expenditure (1 USD = 81 ¥)
NHI (National Health Insurance)	Individual proprietor, pensioner, irregular employer etc.	39 million	1,900	¥10 trillion
Public corporation-run health insurance	Salaried employee of minor enterprises	35 million	1	¥4 trillion
Society-managed employment-based health insurance	Salaried employee of large corporations	30 million	1,500	¥3 trillion
Mutuals	Civil officers	9 million	83	¥1 trillion

Source: GfK Bridgehead

a Market Authorization Holder (MAH) located in Japan. This is a significant improvement from previous laws mandating manufacturing at a company-owned, in-country facility. MAHs, in effect, outsource this responsibility to local Japanese companies. All diagnostics, IVDs, and pharmaceuticals are now subject to this law. MAHs are also responsible for product registration, post-market adverse event monitoring, and quality control in the manufacturing process. In addition to a local MAH, overseas manufacturers must obtain a business license accreditation from the MHLW, which is usually requested by the MAH.

The Pharmaceuticals and Medical Devices Agency (PMDA) is responsible for carrying out the due diligence and recommending reimbursement – as well as regulatory – approval for new medical devices and diagnostics (the final authority rests with the MHLW). Product approval applications must be submitted in Japanese and local clinical trials are often required. The PMDA classifies devices using three classes: Class I (extremely low risk), Class II (low risk), and Class III and IV (medium to high risk). Class I devices do not require product approval or Quality Management System (QMS) evaluation. Class II devices are classified as either Designated Controlled Medical Devices or are undesignated. Designated devices require QMS assessment; however, this can be carried out by a Registered Certification Body (RCB), streamlining the process. Other Class II and Class III devices can be submitted for approval to the prefecture government. Last, class IV devices are assessed by the PMDA itself.

Coding, Pricing, and Reimbursement

The Japanese coding system for diagnostics is similar to the US Center for Medicare and Medicaid Services (CMS) system in that it assigns points and uses a multiplier to derive reimbursement rates. In Japan, in vitro diagnostics are given a point value that is converted into a payment using the Medical Reimbursement Points Table. Medical devices are classified and coded by the Japanese Medical Device Nomenclature (JMDN). These also include codes for diagnostic procedures, such as X-rays, ultrasounds, and MRIs.

Inpatient services are most commonly reimbursed fee-for-service, although Diagnosis Procedure Combination (DPC) codes were introduced by the MHLW in 2003 to encourage case-based reimbursement. DPC coding, which accounts for length of stay, is a more appropriate system than the DRG system due to high variability in hospital length of stay across Japan. 71.7% of DPC codes correspond to a flat hospital fee received as a prospective payment by the hospital, while the remaining 28.3% of overall costs are associated with fee-for-service components tied to physician fees determined by the national fee schedule. Hospital-specific coefficients are generated to adjust DPC codes so that reimbursements are equivalent to those received through fee-for-service billing. Currently 50% of the hospitals in Japan use DPC coding.

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Reimbursement is set based on a medical device's functional category (Table 2). The functional category determines if a device receives a device-specific specialty treatment material (STM) reimbursement in addition to the technical fee a facility receives for all medical devices (except capital equipment and commodities) for the associated procedure. STM payments are based on utility and devices that serve the same therapeutic function are priced identically. Devices can: be covered entirely by technical fees (functional category A1); command supplemental physician fees (A2); generate an additional existing device-specific STM (B); or require new STM and/or technical fees for proper reimbursement (C1, C2). C1 devices are categorised four months after applications are submitted and are initially priced according to comparable products. C2 devices undergo a similar categorization and pricing process, which takes approximately five months.

Table 2: Functional categories of medical devices

Reimbursement Classifications	Description
A1	Included within the technical fee. No separate reimbursement is made for the device itself. Product examples: gloves, gauze, sutures
A2	Technical fee granted for use of the device or class of devices. No separate reimbursement is made for the device itself. Product examples: MRIs, CTs, and most types of capital equipment
B	"Me too" products that are similar to other products on the market. As a result, these products fit into existing technical fee and STM reimbursement categories. Product example: CoCr hip stem
C1	New products based on existing products/therapies. Technical fees exist for the procedure; however, the product itself is a significant improvement vs. prior technologies and is deserving of a new STM reimbursement category. Product example: hip stem using a new material not currently available in Japan
C2	New products that result in a new therapy or procedure. No predicate product or treatment exists. As a result, a new STM reimbursement category and technical fee must be created. Product example: sinuplasty balloon catheter (currently unavailable in Japan)

Source: GfK Bridgehead

The Foreign Average Price (FAP, an average of price in the US, UK, France, and Germany) of comparable devices in the same functional category is then calculated. In recognition of additional market entry costs in Japan, fees may initially be set up to 1.5 times the FAP. However, after two years of initial pricing, prices are subject to reassessment. At that time, if the reimbursement rate is greater than 1.5 times the FAP, the rate will be decreased accordingly. Beyond this, payments are re-evaluated every two years and adjustments are made, although these tend to be minor. All approved devices and diagnostics that are listed in the medical service fee schedule ("Shinryo Hoshu") are covered by insurance.

In practice, the MHLW, who controls reimbursement rates, has cut prices for marketed products by an accumulated 50% since 1998. Recalculation of price is often unpredictable in both timing and outcome. Moreover, aside from initial pricing for the first two years, the fee schedule fails to account for the ongoing higher cost of business in Japan.

Different Strategies

Below are examples of different strategies which certain medtech players have employed to introduce new products into the Japanese market:

Qiagen's *therascreen Kit*

Qiagen, a provider of sample and assay technologies, penetrated the personalized medicine market in Japan using parallel processes; while it sold reagents to an in-country laboratory, it also sought regulatory approval for kit-based assays. Qiagen implemented this strategy through acquisition and domestic manufacturing.

Qiagen's first point of entry was in mid 2008, when Special Reference Laboratories (SRL), one of the largest commercial laboratories in Japan, began offering a KRAS laboratory-developed test (LDT). SRL sought Qiagen's resources due to an unexpected demand for KRAS testing and a limited ability to scale production. Qiagen supported SRL by providing reagents for KRAS testing and improved their automation capabilities. Next, Qiagen acquired a privately-held British company, DxS, in late 2009, which provided Qiagen with the manufacturing capabilities to produce large quantities of companion diagnostic kits.

Qiagen established a partnership with SRL, who converted Qiagen's *therascreen* Kit for use as a homebrew while Qiagen sought regulatory approval of the kit itself. Qiagen received approval for *therascreen* KRAS RGQ PCR kits in April 2011 and began selling them to SRL. Qiagen continues to be successful in the Japanese market and is still the only MAH for commercialised KRAS tests in Japan.

St Jude Medical's Trifecta Valve

St Jude Medical is a global medical device company with major geographic markets including the US, Europe, Japan, and Asia Pacific. With a major St Jude division in Japan and a history of acting as a Japanese distributor for third parties, St Jude is able to avoid many of the administrative regulations faced by foreign companies. However, it is common for St Jude to enter other markets before launching products in Japan.

The Trifecta Valve, a Class IV device in Japan, is an adjustable aortic valve made from bovine pericardial tissue. The Trifecta Valve was first introduced in European markets in March 2010, entered the Canadian market later that year, and was introduced in the US in April 2011. A year later, the company received approval in April 2012 in the Japanese market.

Despite strong market presence and a distribution point in Japan, St Jude Medical's Trifecta Valve was available in several major markets before Japan. The product launch sequence is consistent with other St. Jude Medical products, such as the Epic heart valve and Penta surgical lead, which were available in the US, Europe, Canada, and Australia before Japan.

Facilities that use DPC coding are reimbursed ¥ 20,740 ($256) to ¥ 32,670 ($403) per diem for first-time valve replacements. The average length of stay for a conventional aortic valve replacement is 19.7 days, yielding an average reimbursement of ¥526,089 ($6,482). Comparatively, in the US, the 2011 list price for the 19mm Trifecta valve was $12,000, or ¥979,320.

Terumo Heart's DuraHeart LVAS (Left Ventricular Assist System)

Terumo Heart, a subsidiary of Terumo Corporation, specialises in one device and is based in Ann Arbor, Michigan. Its device, the DuraHeart LVAS, exemplifies the notorious "device lag" in Japan. Terumo Heart began clinical trials for the DuraHeart LVAS in 2004 in Germany and received a CE mark in 2007. Terumo Heart simultaneously planned clinical trials in Japan to address the country-specific evidence requirement. Terumo Heart completed enrollment for its Japanese clinical trials in 2008, a year after the product had already been available on the European market. Terumo then applied for approval from the MHLW in September of 2009 and the device was finally approved by the PMDA in December of 2010. The consequences of the "device lag" can be appreciated in light of the fact that prior to the end of 2010, the only available LVAD covered by the National Health Insurance System in Japan was a pulsatile extracorporeal LVAD approved in 2003. Pulsatile flow is considered first-generation technology and has long been considered inferior to continuous flow, or third-generation LVADs, which are most commonly used in the US.

After approval, the device did receive orphan disease status and a premium for usefulness as well as an upward adjustment based on foreign reference pricing. DuraHeart currently comes with a reimbursement rate of ¥18.1m, or ~$215,000 as of 2012.

Ultimately, careful analysis of market conditions in the disease or technology area can help inform market penetration strategies for devices and diagnostics new to the Japanese market. In some cases, a parallel process may provide entry; in others, new codes and payment rates may be required. As recent and ongoing health reform strives to address issues such as lengthy and complex approval processes, opportunities for novel technologies to enter the large and growing Japanese market will continue to arise.

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