Reimbursement Coverage and Pricing Systems for Single-Use Devices in Asia-Pacific: Japan, Taiwan, Korea, and Australia Compared

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A B S T R A C T

In Asia-Pacific countries, as elsewhere, medical device expenditures account for only a small proportion (between 3% and 6%) of total health care spending per capita [1]. Yet the contribution of medical devices is essential to delivering improved clinical and economic benefits for patients and health care systems, respectively. We briefly report a selective overview of reimbursement coverage and pricing systems for single-use devices (SUDs) in Japan, Taiwan, Korea, and Australia, major Asia-Pacific markets with diverse health care systems but similar challenges. Generally speaking, all four health systems are similar in their framework for managing the coverage and reimbursement of SUDs, which are usually bundled into the overall fee designated for a surgical procedure; however, funding guidelines are unclear and decision-making processes opaque. Unfortunately, this inequitable situation encourages both the dangerous practice of reuse of devices and the imposition of additional out-of-pocket costs on patients. Reimbursement pathways in all four countries need to evolve to accommodate new methods of delivering health care, with fair decision-making processes for reimbursement coverage and pricing, which assess the overall value of medical devices, including SUDs, in terms of health outcomes and/or safety.

Keywords: Asia-Pacific, coverage, pricing, procedure fee, reimbursement, reuse, single-use device.

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Introduction

In general, including in Asia-Pacific countries, medical device expenditures account for only a small proportion (between 3% and 6%) of total health care spending per capita [1]. Yet the contribution of medical devices is essential to delivering improved clinical and economic benefits for patients and health care systems, respectively.

The US Food and Drug Administration broadly defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body" [2]. Similarly broad definitions apply in other countries, and as a result medical devices vary greatly in complexity and application, and different health care systems have similar issues managing their regulation and reimbursement. Various kinds of technologies exist, including prosthetic implants, which replace or modify anatomical functioning and are required over the long term, e.g., coronary stents, pacemakers, and artificial knees, and single-use devices (SUDs), which are nonimplantable and not designed for reuse and vary in sophistication from having a specific therapeutic or diagnostic use (e.g., atrial fibrillation ablation catheters and drug-coated balloons) to devices acting as adjuncts to the delivery of therapeutic interventions (e.g., catheters, guidewires, and sheaths) to “consumable items” (e.g., disposable plastic syringes and latex surgical gloves). As the uses and roles of SUDs increase, their effects on reimbursement coverage and pricing processes and policies are in growing need of attention from health authorities and other payers.

Four Asia-Pacific countries, Japan, Taiwan, Korea, and Australia, have diverse health care systems with unique challenges for patient access to medical services but also share similarities (Table 1). Here, we briefly report a selective overview of reimbursement coverage and pricing systems for SUDs in these major Asia-Pacific markets, where comprehensive public or private health care systems exist.

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Japan

Japan has a national health insurance system, and medical devices are mostly paid for under a “fee-for-service” scheme. Reimbursement decision-making processes and prices differ by product group. Medical devices available in Japan are classified by generic name, which provides a broad definition of the device with further subdivision based on risk category. Most low-risk medical devices (i.e., US Food and Drug Administration class I and II devices) do not have separate reimbursement prices and their payment is included in the procedure fee (which also includes patient management fees); likewise, low-risk SUDs are bundled into the procedure fee. Manufacturers must submit a reimbursement application to the Ministry of Health, Labor and Welfare (MHLW) for their SUD device to be covered by particular procedure fees. Medium- and high-risk SUDs, in general, have their individual reimbursement prices determined by the MHLW on the basis of the “functional category” system. Functional category is determined by the MHLW, but reflects the opinion of the Central Social Medical Insurance Council (“Chuikyo”), which also determines which medical devices are to be included under national insurance. The criteria for defining the functional category of a device are based on similarity in structure, purpose of use, efficacy, and effectiveness/performance. Manufacturers need to submit an application to the MHLW to get their devices into an existing functional category (if an applicable one exists) to be covered by reimbursement. If a new medical device does not fit into an existing functional category and/or corresponding procedure fee, manufacturers need to submit an application to the MHLW to create a new functional category or to develop both a new functional category and a new procedure fee to acquire reimbursement for their device.

Taiwan

Taiwan has a national health insurance system, and medical devices are paid for either under a fee-for-service or a Diagnosis Related Group (DRG)-based scheme. Medical devices are reimbursed on the basis of a functional category classification, with the categories defined by the National Health Insurance Administration using criteria based on similarity in structure, purpose of use, efficacy, and performance [4]. The Pharmaceutical Benefits and Reimbursement Schedule committee, composed of various stakeholders, reviews reimbursement coverage, the proposed price, and any restrictions; however, the National Health Insurance Administration makes the final decision on reimbursement coverage and price. With the amended and promulgated “Second Generation” National Health Insurance Act in 2011, a “Balance Billing” system was introduced so that patients would take greater financial responsibility for expenditure on more costly medical devices. The National Health Insurance Administration makes the decision on the reimbursement price of new devices by comparing the prices of currently listed devices and referring to the reimbursement or market prices in other countries [5].

Reimbursement coverage decisions for medical devices are classified into three categories: “reimbursed,” “funding under procedure fee,” and “unreimbursed (funded by patients out-of-pocket).” Many SUDs are placed in the funding under procedure fee category. Unfortunately, Pharmaceutical Benefits and Reimbursement Schedule decisions about SUDs are often made without clarity of procedure or process, and are therefore unpredictable, making it difficult for manufacturers to plan their reimbursement application strategy. The overall result of funding SUDs under procedure fees creates a market entry barrier, and, worse, encourages the unsafe practice of reusing SUDs.

Korea

Korea has a national health insurance system, and medical devices are paid for under a fee-for-service or a DRG-based scheme (though the latter is limited to only seven disease groups). Medical devices are reimbursed on the basis of functional category, with the categories defined by the Ministry of Health and Welfare (MoHW) after considering indication for use and three physical characteristics: compositional material, shape, and size [6]. The formal decisions about reimbursement coverage and price are made by the MoHW, but in practice the decisions are made by the Medical Device Expert Evaluation Committee within the Health Insurance Review and Assessment Services. Medical Device Expert Evaluation Committee’s reimbursement
Australia

Australia has both a national tax-based health system and a voluntary private health insurance system. In the national health system, medical devices are funded within a DRG-based prospective case payment, which includes hospital and physician costs. Medical devices are predominantly supplied under tendering arrangements, and the range and choice of device can be limited. However, in the private health insurance-based system, medical devices are mainly funded via the Prostheses List (PL), a register of devices administered by the Department of Health. Private health insurers are required to pay a “benefit” (reimbursement) for a prosthesis that is provided as part of an episode of inpatient hospital treatment but only if the device is included on the PL. The relevant legislation does not define a “prosthesis”; instead, criteria for listing products on the PL are applied to each medical device assessed on application for listing.

The PL is based on a functional category system and lists both the medical devices and the corresponding benefit amounts that private health insurers are required to reimburse (in addition to the predominantly DRG-based payment for hospital charges). Within the various functional categories listed on the PL, medical devices are grouped according to the features and characteristics that define their clinical effectiveness. Medical devices considered to have similar clinical effectiveness are listed with similar benefits (reimbursement prices).

Unfortunately, SUDs with a specific therapeutic or diagnostic use (also known as “high-cost disposable products”) are not eligible for inclusion on the PL because they are not surgically implanted or remain with the patient after discharge from hospital. Under the DRG model, funding for these devices is bundled into the overall case payment. Unlike most surgical theater consumables, which are routinely used and relatively cheap, however, sophisticated SUDs tend to be of higher cost, and without mandated additional payments to cover their costs, access to SUDs is determined by individual contractual arrangements between the private health insurer and the private hospital. As a result, patient access to SUDs varies across the country, for example, access to catheter ablation devices for the treatment of atrial fibrillation. The difference in funding arrangements for implanted versus nonimplanted devices also risks creating a perverse incentive to use potentially less effective and in the long run perhaps more costly treatment options, for example, stents (separately reimbursed) instead of drug-coated balloon technologies (DRG-funded) to treat peripheral and coronary arterial disease [8].

Discussion

The four Asia-Pacific countries reviewed here display both similarities and differences in the elements of reimbursement coverage and pricing decision making for implantable devices and SUDs. Japan, Taiwan, and Korea in particular have very similar frameworks in terms of the overall management of SUD coverage and reimbursement. Although many SUDs are grouped in a category that provides for separate funding, a considerable number are bundled into the procedure fee; this raises a number of problems, as outlined above.

There are other important issues around how SUDs are funded and accessed. First, the countries reviewed do not have clear guidelines and processes for managing the reimbursement of SUDs. There are no clear criteria for determining which reimbursement category SUDs will be funded under. This often results in poor transparency of decision making, and uncertainty for manufacturers and other stakeholders.

Second, although health authorities systematically evaluate the clinical and economic value of most implantable devices, they usually do not assess SUDs in the same way but simply bundle them into procedure fees. As a result, the benefits of innovative SUDs, as well as their costs, are not properly considered.

Third, inequitable funding arrangements for SUDs raise the risk of two different but serious issues that may have an impact on patients: the problem of reuse of devices not designed to be safely recycled, and the imposition of out-of-pocket payments on patients, both a result of health care providers attempting to keep costs within procedure fee thresholds.

Conclusions

The four Asia-Pacific countries reviewed here do not have equitable arrangements for managing the reimbursement of sophisticated SUDs, and the processes currently in place run the risk of encouraging the unfair practice of demanding out-of-pocket payments from patients, and, worse, the dangerously unsafe practice of recycling devices. What are required are clear guidelines for reimbursement coverage and pricing, and transparent and fair evaluation and decision-making processes, so that the value of an SUD, in terms of health outcomes and safety, is properly taken into account. This requires reimbursement pathways in all four countries to evolve to accommodate new treatment options and methods of delivering health care, which may be less invasive and resource intensive due to innovative SUDs (e.g., ablation catheters now provide an alternative treatment option to open surgery for Barrett’s esophagus). One way forward may be to develop processes that do not separate implantable from nonimplantable devices but focus more on assessing holistically the value device products bring to patients and health care providers and payers, and linking this to reimbursement support, so that the use of a particular device is based on the most appropriate treatment option rather than the somewhat arbitrary availability of funding.
This paradigm shift also requires manufacturers to take responsibility for developing the clinical and economic evidence necessary for health care providers and payers in the four markets reviewed here to understand the value of a new technology, and particularly how it compares to alternative treatment options. Reimbursement and pricing decisions can then be transparently and rationally made on the basis of evidence rather than artificial barriers based on inflexible and out-of-date criteria.

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REFERENCES


