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Medical Device Reimbursement Coverage and Pricing Rules in Korea: Current Practice and Issues with Access to Innovation

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ABSTRACT

The development of health funding policy in Korea has followed the country's rapid economic development, with a comprehensive National Health Insurance (NHI) system in place by 1989. The funding of medical devices has followed this progression, with incorporation into the NHI reimbursement system in 2000 (several years later than pharmaceuticals), but important issues affecting patient access remain. Although the effect of devices on the NHI budget is relatively modest (only about 4%), because of concerns about NHI sustainability, attention has increasingly been paid to their management and funding. Unlike pharmaceuticals, however, it has been quite challenging to develop clear and fair criteria for reimbursement coverage and pricing of medical devices. The two key and longstanding issues around the reimbursement of medical devices in Korea are how to expedite market entry of improved or innovative medical devices at appropriate prices, and how to satisfactorily lower the reimbursement levels of older devices, thereby making headroom for new technologies to be reimbursed. Despite protracted discussions over the last decade, industry and government have been unable to reach full agreement. There has been some progress (e.g., introduction of the Value Appraisal and the Revaluation Systems), but there remains urgent need for productive discussion and consensus between government and industry regarding reasonable funding rules, transparency, and clarity in the reimbursement pricing process for medical devices.

Keywords: coverage, Korea, medical device, patient access, pricing, reimbursement.

Introduction

The development of health funding policy in Korea has followed the same trajectory as the country's economic development, with the inaugural Medical Insurance Act enacted in 1966 and implemented in 1977, a universal Medical Insurance System introduced a mere 12 years later, and transformed since 1989 into a comprehensive National Health Insurance (NHI) system. The reimbursement of medical devices has expanded along with this progression in Korean health, but important issues affecting patient access remain. In this policy perspective article, the current reimbursement coverage and pricing rules, and the decision-making process are briefly discussed and the major access issues that remain are outlined.

Reimbursement Decision Making

As a statutory requirement to enter the Korean market, medical devices must first be licensed by the Ministry of Food and Drug Safety, which, like its international regulatory counterparts in the United States and elsewhere, undertakes classification and risk-based assessment of the quality, safety, and efficacy of products [1]. The Ministry of Food and Drug Safety (previously the Korea Food and Drug Administration) follows similar US Food and Drug Administration classification, with devices categorized from class I (general controls) to class IV (requiring premarket approval).

Applications for reimbursement of a medical device must be made to the Ministry of Health and Welfare (MOHW) within 30 days of regulatory approval by the Ministry of Food and Drug Safety. The Health Insurance Review and Assessment Services (HIRA) and its Medical Device Expert Evaluation Committee (MDEEC) review the application and make a recommendation to the MOHW, which decides reimbursement coverage and price (Fig. 1 and Table 1). Officially, the lead time for reimbursement approval is 150 days; however, it usually takes significantly longer, particularly for devices that require health technology assessment (HTA) evaluation before application review (because the device and the associated procedure undergo separate reviews, see below) and for new devices that require the establishment of coverage guidelines (specifying the clinical indication, etc.).

Under the Korea-US Free Trade Agreement (which took effect March 15, 2012), suppliers may appeal MDEEC decisions through an independent third-party review process introduced to enhance transparency and objectivity [2]. The process, however, is unappealing to suppliers because the lead time is also nominally 187 days and the findings are not legally binding on the MOHW.

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* The Health Technology Assessment (HTA) process is limited to medical devices associated with new procedures or techniques, and for which comparable products are unavailable.

Fig. 1 – Flow chart for the medical device reimbursement approval process.

Issues

Although the number of devices listed for reimbursement has steadily risen, the rate of reimbursement has not been in step with the number of applications being made (currently more than 100/month). For instance, over the period 2010 to 2012, reimbursement applications grew at about 17%/year but listings increased by only about 9% annually—and overall medical devices continue to make up only about 4% of total NHI expenditure (the size of the private, out-of-pocket, sector is unknown, with no official statistics because government is not concerned with price or utilization controls).

A particular difficulty is that HIRA has adopted a policy of requiring robust evidence of efficacy, safety, and cost-effectiveness as a prerequisite for a positive reimbursement recommendation (Table 2). This poses a major problem for the medical device sector, in which historically (unlike pharmaceuticals) there has not been demand for rigorous economic and other evidence, and therefore the Value Appraisal Standard 2 (VAS 2) criteria were introduced for applications requesting premium prices (see below).

The MOHW announced revised regulations on February 25, 2013 (effective April 1, 2013) [3]: first, to expedite market entry, the reimbursement application process was shortened by differentiating submissions on the basis of product characteristics and the likely level of review complexity—a positive development welcomed by industry. Second, the MDEEC was reorganized 1) with its pool of experts increased to 300 members (nominated by medical societies and relevant stakeholders) to enhance expertise, objectivity, and fair and efficient operation; and 2) with experts to attend monthly meetings to be randomly selected from the pool and increased in number to 20. This latter reform was opposed by all nongovernment stakeholders on the grounds that the random selection of experts for each reimbursement meeting was likely to result in inconsistent and poor decision making (previously MDEEC meetings were attended by 18 experts, each of whom served a 2-year term). Nevertheless, the new arrangements were implemented.

Reimbursement Pricing Mechanism

Reimbursement decisions about new devices are usually made on the basis of comparisons with devices already on the MOHW list, "unreimbursed" devices (these are also listed, making up about 10% of the total), and the relevant procedure fee. New devices are then placed into one of three categories: reimbursed, funded under the procedure fee, and unreimbursed.

"Reimbursed" category: A device is reimbursed by brand, with its own code and price, and can be claimed for separately. The reimbursement level is determined by comparing the product with those already listed and in the same "functional category." In this context, the functional category of a medical device is determined by considering both its indication for use and three physical characteristics: compositional material, shape, and size; for instance, all pacemakers, regardless of manufacturer and brand, are placed in the same functional category. Most new medical devices are determined at the lowest price, or 90% of the

Table 1 – Medical device reimbursement approval process.

Step	Process	Process description
1	Reimbursement application must be submitted within 30 d after Ministry of Food and Drug Safety (MFDS) approval	Application to the Ministry of Health and Welfare (MOHW) or Health Insurance Review and Assessment Services (HIRA). Manufacturers, medical institutions, and medical societies may submit applications.
2	HIRA review	Review of appropriateness of coverage and reimbursement price. Consideration of eligibility for reimbursement and estimation of budget impact. Review of comparable devices already listed. Comparison of cost-effectiveness with currently listed devices (by reviewing the application, the literature, seeking medical society opinion, etc.). Collation of internal/external expert opinion.
3	Medical Device Expert Evaluation Committee (MDEEC) review	Recommendation on reimbursement coverage and price made within 100 d of application. Consideration of economic feasibility (i.e., substitutability and cost-effectiveness) and appropriateness for funding.
4	Health Insurance Policy Deliberation Committee (MOHW)	Confirmation of decision about reimbursement coverage and price.
5	Publication of reimbursement approval notice	Approval notice published on the MOHW Web site within 150 d of application.