

Japanese reimbursements fail to send the right signals to orthopaedic firms



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In Japan, orthopaedic products are classified into a few broad reimbursement categories. More specific categories and greater flexibility could free the market and close the so-called device gap, writes Derrick Buddles, member of the Orthopaedics Committee at the American Medical Devices and Diagnostics Manufacturers' Association (AMDD)

The pricing of a product involves striking a balance between the value users get from that product and the levels of investment, risk and reward that fall to the producer. Get the pricing right, and both user and supplier will be happy. Get the pricing wrong, and chances are both parties will end up dissatisfied. But it is not just the absolute price of a product that is important; the way products are priced relative to each other has implications for product availability and consequences for different stakeholders.

Most orthopaedic implants in Japan must be approved for reimbursement before they may be sold, in addition to meeting safety and efficacy requirements. Once fully approved, a product is reimbursed according to an amount stipulated by Japan's Ministry of Health, Labour and Welfare's Special Treatment Materials (STM) classification system.

The STM system classifies orthopaedic implants according to their physical or biological functions. What is striking about orthopaedic implant categories in Japan is the breadth of those categories – they are so broad that all cementless hip stems are included in a single category and reimbursed at a single amount. Whether the stem in question boasts an added porous structure, a biological coating or modular features, or is a revision versus primary product, has no bearing on its category and therefore no bearing on the amount for which it is reimbursed. In fact, all the total hip and total knee components sold in Japan – running into the thousands – are shoe-horned into the list of categories in Table 1.

Structuring reimbursement categories in this catch-all way undermines the normal pricing mechanism through which added functionality, expanded system options or variants for rare medical conditions would be encouraged; that is, by

attracting some level of premium pricing. It also fails to signal where new forms of low-cost devices might be needed for low-demand situations.

There is evidence that the MHRA's pricing mechanism may be affecting product availability in Japan. A study by the American Chamber of Commerce in Japan's Medical Devices and Diagnostics Subcommittee found that Japan suffers what is called a device gap, which means that only 50% of the products available in the US or CE marked for sale in Europe were available in the country. For 36% of available products in the US, suppliers in Japan did not even bother to submit approval applications. They cited six core reasons, namely lack of resources, unattractive reimbursements, high cost of business, anticipated time lag, insufficient demand, and high regulatory costs, among

others. While this blanket approach to reimbursement has the advantage of simplifying pricing adjustments for the authorities, a properly functioning market would flag up unmet needs deemed by purchasers to be worthy of attention.

One solution to this lack of communication from the market is for the authorities in Japan to allow far greater use of the C1 and C2 reimbursement processes, under which new products with new technologies and new functions are given new reimbursement categories. This would generate information and spur manufacturers to bring products to or develop products for Japan that represent value to patients, medical professionals and hospitals. It would propagate new cost-saving ideas, which are so important to the long-term wellbeing of the healthcare system in Japan.

Table 1. Japanese reimbursement categories for total hip and total knee components

Total hip replacement components*	Total knee replacement components*
Cementless acetabular cup	Cementless femoral
Cemented acetabular cup	Cemented femoral
Cemented cup/liner (all poly)	Cemented femoral (low wear type)
Cup liner	Patella
Cup liner (low wear type)	Patella (low wear type)
Cementless hip stem	Tibial insert
Cemented hip stem	Tibial insert (low wear type)
Femoral stem head	Cementless tibial
Options (sleeves, screws)	Cemented tibial
	Options (stems, wedges...)

*Excludes endoprosthesis and unicondylar knees