

Analysis of the Gap between Submitted and Determined Reimbursement Prices of Innovative Medical Devices in Japan

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Summary

Reimbursement prices, which are determined by the Minister of Health, Labour and Welfare under the universal healthcare system in Japan, play an important role in driving innovation. In connection with this, there have been discussions at the Special Committee of the Central Social Insurance Medical Council on the topic of evaluation of innovation.

The objective of this study is to examine the gap in reimbursement prices between those requested by enterprises and those set by the government in the current system and to clarify the factors that contribute to this gap, in order to identify factors that drive medical device innovation.

In this study, we focus on medical devices that were determined to belong to insurance coverage category C from October 2004 to March 2016 (291 devices, 332 parts). We devise a novel index, called the gap index, based on the requested price and the determined price, to capture the gap in medical device reimbursement prices between the government and enterprises in Japan. We perform multiple regression analysis to explore the factors that contribute to the gap.

We found that gaps occurred in 90% of cases. Multiple regression analysis showed that five variables (calculation method, approval year, premium for usefulness, premium for improvement, and cross term of calculation method and premium) are statistically significant. The correlation coefficient of the gap index and the revision rate of the medical device reimbursement budget in the revision fiscal year was -0.93.

These results suggest that the major contributing factors to the gap are: uncertainty of the cost accounting method, uncertainty of the premium requirement, change in the function classification, and the calculation method used during the review process. The gap index and the medical device budget revision rate are highly correlated and the budget revision rate influences the gap in reimbursement prices.

Key words

Medical device, Innovation, Reimbursement, Value based pricing, Japan