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Evolution and Key Issues of the Medical Device Reimbursement System in Japan

(Executive Summary)

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This paper traces the historical evolution of Japan's reimbursement system for medical devices, analyzes key issues such as innovation evaluation, international price disparities, technical fee assessments, and cost-effectiveness evaluations, and provides recommendations for the future of the system.

1. Basic Framework and Current Challenges

The current framework, centered on the "Functional Category System" and the "Weighted Average Market Price plus Reasonable Margin" method, was established following the 1993 Central Social Insurance Medical Council (Chuikyo) recommendations. While Specific Treatment Materials (STM) are reimbursed at a flat rate based on functionality, this system faces challenges, including reduced business predictability for companies and a failure to reflect technological superiority in pricing.

2. Advancement of Innovation Evaluation

Since the late 2000s, the evaluation of innovation has become a central pillar of medical policy. This led to the introduction of premiums for improvements and accelerated reimbursement listing. Recent developments include the "Challenge Application" system, which allows for post-listing re-evaluation based on clinical evidence, and "Economic Efficiency Premiums" for cost-saving technologies.

3. Shift from Foreign Price Gaps to "Negative Margins"

Historically, Japanese medical device prices were criticized for being higher than foreign prices, leading to strict price suppression via the Foreign Average Price (FAP) system. However, recent yen depreciation and global inflation have triggered a reversal, resulting in "Inverse Price Gaps" (where Japanese prices are lower than abroad) and "Negative Margins" (where market prices exceed reimbursement rates). The 2026 revision marked a historical turning point, introducing rules to raise reimbursement prices under specific conditions for the first time in 30 years.

4. Cost-Effectiveness and Transparency in Technical Fees

The Cost-Effectiveness Evaluation (HTA) system, fully implemented in 2019, follows a unique Japanese model of post-listing price adjustment. While the rules consider the learning curve of medical devices, the lack of sufficient clinical data remains a hurdle. Furthermore, compared to STM, the evaluation process for medical devices bundled into "Technical Fees" (lump-sum payment) lacks transparency, necessitating future reforms.

5. Conclusion and Recommendations: Sustaining Innovation

The authors propose the following two directions for future policy:

- Consideration of Bundled Payments(lump-sum): Moving toward comprehensive payment systems for surgeries and procedures, similar to those in the US and Europe, to allow market principles to drive appropriate pricing.
- Expansion of "Selected Medical Care": Allowing flexible use of the SMC framework (where patients opt to pay the difference for added value) for benefits that public insurance cannot fully cover, such as enhanced QOL or convenience. This would help maintain incentives for R&D.

The paper concludes that Japan may transition from being a "free rider" on US-led R&D to a global contributor. As a "frontrunner" in aging demographics, Japan should provide appropriate reimbursement and clinical data to foster global innovation and support its domestic medical device industry.

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