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## Development of an Official Guideline for the Economic Evaluation of Drugs/Medical Devices in Japan

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### ABSTRACT

**Objectives:** In Japan, cost-effectiveness evaluation was implemented on a trial basis from fiscal year 2016. The results will be applied to the future repricing of drugs and medical devices. On the basis of a request from the Central Social Insurance Medical Council (Chuikyo), our research team drafted the official methodological guideline for trial implementation. Here, we report the process of developing and the contents of the official guideline for cost-effectiveness evaluation.

**Methods:** The guideline reflects discussions at the Chuikyo subcommittee (e.g., the role of quality-adjusted life-year) and incorporates our academic perspective. Team members generated research questions for each section of the guideline and discussions on these questions were carried out. A draft guideline was prepared and submitted to the Ministry of Health, Labour and Welfare (MHLW), and then to the subcommittee. The draft guideline was revised on the basis of the discussions at the subcommittee, if appropriate.

**Results:** Although the “public health care payer’s perspective” is standard in this guideline, other perspectives can be applied as

necessary depending on the objective of analysis. On the basis of the discussions at the subcommittee, quality-adjusted life-year will be used as the basic outcome. A discount rate of 2% per annum for costs and outcomes is recommended. The final guideline was officially approved by the Chuikyo general assembly in February 2016. **Conclusions:** This is the first officially approved guideline for the economic evaluation of drugs and medical devices in Japan. The guideline is expected to improve the quality and comparability of submitted cost-effectiveness data for decision making.

**Keywords:** cost-effectiveness analysis, discount, guideline, productivity loss, QALY.

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### Introduction

Economic evaluation previously was largely unused in decision making as applied to the reimbursement or pricing of health care technologies (e.g., drugs, medical devices, and interventions) in Japan. Ever since 1992, when new medicines are added to the reimbursement list for public health care insurance, economic evaluation data can be submitted to the Ministry of Health, Labour and Welfare (MHLW; Ministry of Health and Welfare at the time). However, in Japan, almost all approved drugs are automatically reimbursed without referring to cost-effectiveness data. In addition, there is a lack of clear rules regarding how to use the submitted data for pricing. Therefore, even if economic data are submitted, many pharmaceutical companies do not believe that such data are reflected in the decision making on their products. As a result, economic data for only 8 new drugs were submitted to the MHLW from fiscal year (FY) 2006 to 2011,

although reimbursement for 256 drugs was provided during the same period. With respect to medical devices and interventions (e.g., diagnosis and surgery), the MHLW requests economic data for reimbursement, but for the most part, these analyses merely compare costs (cost analysis) or are used for cost minimization (Table 1) [1].

In Japan, the official price of drugs and medical devices is determined by two methods: the cost calculation method and the similar efficacy comparison method. If a new product is rated as innovative, a premium can be applied to the daily price of a comparator (similar efficacy comparison method) or profit rate of a product (cost calculation method). The official price is revised every 2 years on the basis of results of the market price survey. Such prices and pricing systems for medicines, and devices are determined (strictly speaking, advised to the minister of MHLW) by a council established by the MHLW called the Central Social Insurance Medical Council (Chuikyo). From FY2012, discussions on

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**Table 1 – Present state of economic evaluation submitted to the MHLW [1].**

Analysis	Medicines*	Medical devices†	Interventions‡
CEA with QALY	3	1	0
CEA with other outcomes	4	1	0
Cost-benefit analysis	0	1	0
Others (e.g., cost analysis, cost minimization)	1	20	125
Total	8	23	125

CEA, cost-effectiveness analysis; FY, fiscal year; MHLW, Ministry of Health, Labour and Welfare; QALY, quality-adjusted life-year.

\* Data only for 8 new drugs, reimbursed from FY2006 to FY2011.

† There were 23 new devices with new functions, reimbursed in FY2011.

‡ There were 125 interventions for which requests were sent for inclusion in the reimbursement list by academic societies in FY2011.

economic evaluation began within a subcommittee of the Chuikyo, that is, the Special Committee on Cost-Effectiveness Evaluation, which consists of 16 individuals (6 representatives of health care payers, 6 health care professionals, and 4 public interest [e.g., academics]), in addition to 4 industries and 3 health economists (coauthors: T. Fukuda, S. Ikeda, and T. Takura) as nonvoting members. Japan is one of the fastest aging countries in the world, and consequently suffers from a rapid rise of health care expenditures. This situation is exacerbated by newly developed and high-priced health care technologies such as anticancer and antihepatitis drugs. Despite this, cost-effectiveness has not been extensively used for health care policy decision making. Over the course of 4 years of discussions, the Chuikyo subcommittee members reached a consensus that cost-effectiveness evaluation (MHLW refers to economic evaluation as such) should be implemented on a trial basis from FY2016. The results will be applied to the future repricing of drugs and medical devices. According to their discussions, demonstrating the validity of official prices determined by the government from the perspective of cost-effectiveness is important. They also requested the consideration of a full-scale implementation and to expand the target technology to interventions using expensive devices by FY2018, that is, the year in which the pricing system is scheduled to be revised next. These activities are supported by the Basic Policy on Economic and Fiscal Management and Reform 2015 [2] as part of the Japanese government's policy.

In the trial implementation of cost-effectiveness evaluation, manufacturers are requested to submit economic data to the MHLW. This evaluation, however, does not target all drugs and devices. Target products are determined by the Chuikyo, and selection criteria have already been set. First, regarding listed technologies for which reimbursement decisions were made between FY2012 and FY2015, four categories were set as target criteria for the recalculation of prices: 1) the highest premium rate, 2) 10% or more premium and the highest sales, in both of two pricing methods (the cost calculation method and the similar efficacy comparison method), excluding rare intractable diseases. The results of this evaluation are to be reflected in official prices with the next revision (in FY2018). Nevertheless, how to reflect the results has not yet been determined. This issue will be discussed by the Chuikyo and a consensus will be reached by the end of FY2017. Second, evaluations will be submitted for newly reimbursed technologies from FY2016 with the expectation of large sales to serve as reference material, and will not be reflected in official prices.

To apply the results of economic evaluation to health care decision making, there is a need to standardize the methods of cost-effectiveness evaluation. In the absence of guidelines, the methodology and quality of economic evaluation may vary widely. This leads to low comparability across different analyses, as well as low-quality analyses. An official guideline for economic

evaluation has yet to be established in Japan, although our research team previously developed a guideline for academic researchers [3]. Many regions in Asia, such as Korea [4,5], Taiwan [6], and Thailand [7], as well as European countries have official guidelines. For this reason, our research team was asked to develop a methodological guideline for cost-effectiveness evaluation by the Chuikyo for trial implementation. Our submitted draft guideline was approved by the Chuikyo, and as a rule manufacturers must carry out the analysis stipulated by the guideline. When difficulties arise with following the guideline, manufacturers are asked to have a preliminary consultation with authorities to discuss the analysis method. Here, we report the process of developing and the contents of the official guideline for cost-effectiveness evaluation.

## Process and Methods

Main methodological issues were continually discussed at meetings of the Special Committee on Cost-Effectiveness Evaluation of the Chuikyo (hereafter, "subcommittee") from FY2012. Most of the subcommittee members were not experts in economic evaluation, and some members had competing interests with each other. Three coauthors explained the concept of economic evaluation and technical terms, answered questions, and provided comments from the perspective of experts. These discussions led to the official publication of two interim reports from the subcommittee in September 2013 and August 2015. By August 2015, members of the subcommittee had reached a consensus on the following four points: 1) choice of outcomes, 2) range of costs, 3) comparators, and 4) data sources. The choice of outcomes was one of the most controversial issues within the subcommittee. On one hand, some members such as from medical associations and the industry strongly opposed the mandatory use of quality-adjusted life-year (QALY), as required by the National Institute for Health and Care Excellence (NICE) in England/Wales. On the other hand, some members, including insurers and health economists, supported the use of QALY. After long deliberations, a consensus was reached on the function of QALY, that is, QALY should be used as a basic outcome, but other outcomes are allowed to be used depending on the characteristics of the technology.

The second point was addressed as follows: Productivity loss should not be included in the costs in base-case analysis. According to subcommittee discussions, the estimation of productivity loss is less reliable because such loss largely varies depending on the estimation method. In addition, if productivity loss is much greater than the health care costs, the productivity loss would account for the major part of the cost. This makes it difficult to evaluate public health care expenses. The consensus regarding the third point was that the health care technology that is replaced by a new one and is used widely in clinical practice

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