

Overview of Cost Effectiveness Evaluation System of Pharmaceuticals and Medical Devices in Japan 日本における医薬品・医療機器の費用対効果評価制度の概要



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東京大学医学部保健学科卒、同大学院医学系研究科保健学専攻博士課程修了。東京大学医学部保健管理学教室助手、同大学院薬学系研究科医薬経済学客員助教授、同医学系研究科臨床疫学・経済学准教授を経て、2011年より国立保健医療科学院上席主任研究官、2015年同医療・福祉サービス研究部長。2018年に保健医療経済評価研究センターが開設されたことに伴い、同センター長。専門領域は、医療経済、医療管理、薬剤経済。

Takashi Fukuda received his PhD degree from the Graduate School of Medicine, the University of Tokyo, majored in Health Sciences. After his career as Associate Professor of the Department of Health Economics and Epidemiology Research, School of Public Health, the University of Tokyo, he works for the National Institute of Public Health since 2011. He became Director of the Department of Health and Welfare Services in 2015. As new Center for Outcomes Research and Economic Evaluation for Health(C2H) was opened in 2018, he was appointed as the first director of the center. His major research areas are health care economics, health care administration, and pharmacoconomics.

中央社会保険医療協議会における約10年の議論を経て、2019年4月より医薬品・医療機器の費用対効果評価制度が開始された。本制度では、薬価や材料価格算定上の加算や市場規模予測などの一定の要件を満たした品目を選定し、費用対効果の評価を行った上で、必要に応じて価格調整をするしくみである。指定された品目については、まず製造販売業者が分析を行い、これを検証・再分析して最終的な評価結果を導くようになっている。制度開始から約3年が経過し、いくつかの品目については評価結果が出てきている。本制度の概要を紹介する。

After 10 years of discussion at the Central Social Insurance Medical Council, a new cost effectiveness evaluation system of pharmaceuticals and medical devices was institutionalized in April 2019. In the system, target products are pharmaceuticals and medical devices which are applicable to the premiums in price setting and have high expected annual sales. Manufacturers of those products are asked to submit their data and analyses first. They will be reviewed and re-analyzed by public organization. Based on the results of cost effectiveness analysis, the reimbursement price will be adjusted if necessary. Analyses of several products were already finalized and prices were adjusted. Overview of the new system will be introduced.

Overview of Cost Effectiveness Evaluation System of Pharmaceuticals and Medical Devices in Japan

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History on the discussion of cost-effectiveness evaluations

Around 2010- Discussions at the Central Social Insurance Medical Council (Chuikyo) on the introduction of cost-effectiveness evaluations

May 2012 **Special Committee on Cost-Effectiveness Evaluation established under Chuikyo**

June 2015 In the "Basic Policies on Economic and Fiscal Management and Reform 2015", it was decided that cost-effectiveness evaluation would be introduced on a trial basis at the 2016 Revision of Medical Service Fees.

April 2016 **Trial introduction of cost-effectiveness evaluations**

June 2018 In the "Basic Policies on Economic and Fiscal Management and Reform 2018", it was decided that the full-scale introduction of cost-effectiveness evaluations continues to be considered, and a conclusion should be reached within FY 2018.

April 2019 **Full scale introduction of cost-effectiveness evaluations**

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Summary of new Cost Effectiveness Evaluation System

- Started in April, 2019
- Medicines and Medical devices
- After the approval, products are reimbursed under health insurance scheme in accordance with current pricing rules. The price may be adjusted after cost effectiveness evaluation.
- Products with large expected annual sales or prominently high price are subject to evaluation.
- Products only for rare diseases or children are exemption from evaluation.
- The price will be adjusted when ICER exceeds JPY 5 million /QALY. (JPY 7.5 million/QALY for such products as anti-cancer drugs.)

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Selection criteria for products targeted for cost-effectiveness evaluations

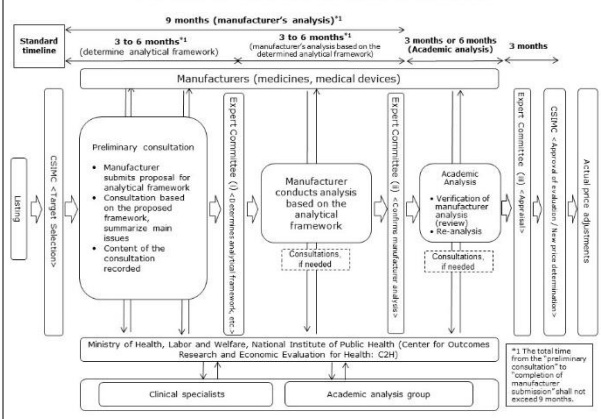
| Classification | Similar Efficacy Comparison Method (Similar Function Classification) | Cost Calculation Method | Selection Criteria |
|--|--|--|---|
| (I) New Listed Products: after full-scale implementation | H1 | Products with premium ^(*) , or disclosure rate of under 50% | • Peak sales (estimate): JPY 10 billion or more |
| | H2 | | • Peak sales (estimate): JPY 5 billion or more, under JPY 10 billion |
| | H3 | | • Products determined by the CSJMC General Assembly, such as products with a prominently high price |
| (II) Already listed Products: before full-scale implementation | H4 | Products with premium ^(*) | • products with sales of JPY 100 billion or more • Products determined by the CSJMC General Assembly, such as products with a prominently high price |
| | Similar products | H5 | Similar products in the H1-H4 Classification |

^(*) Products for which either an innovativeness premium, utility premium, or improvement premium (medical devices) was calculated will be targeted

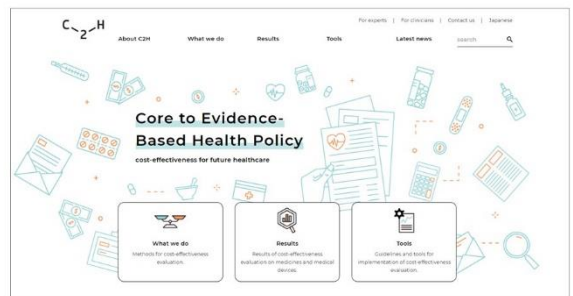
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Process for cost-effectiveness evaluations



More Information <https://c2h.niph.go.jp/en/>



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