

Speaker



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HTA Development in Japan

HEALTH TECHNOLOGY ASSESSEMENT AND HEALTH POLICY:
RECENT DEVELOPMENTS ACROSS ASIA
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Medical Expenditure in Japan

Public health insurance scheme covers whole population.

Health insurance bodies consist of occupational based and community based.

In 2012,

Annual Medical Expenditure : JPY 39,212 billion
8.3% of GDP

307,500 yen/capita



Health Insurance Coverage and Pricing

- Health insurance coverage decision and reimbursement prices are determined by the Ministry of Health, Labour and Welfare (MHLW), not depend on health insurance bodies.
- Prices are revised every two years.
- MHLW has to consult with Central Social Insurance Medical Council (Chu-I-Kyo.)



Central Social Insurance Medical Council (Chu-I-Kyo)

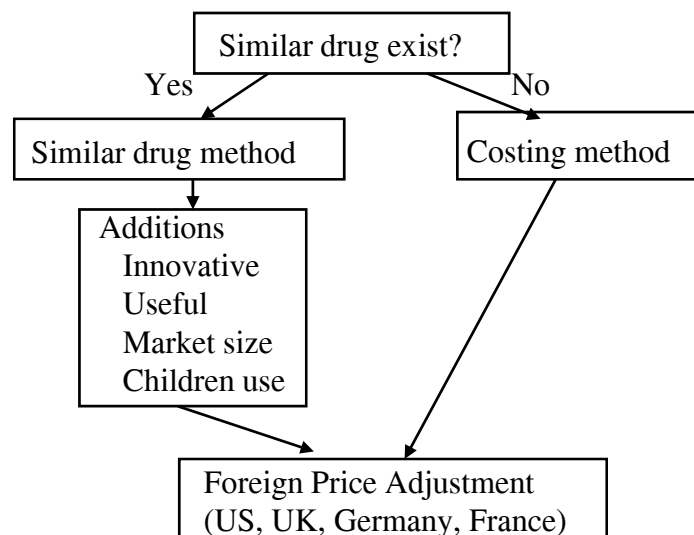
7 representatives from health care insurers
employees health insurance, community
based health insurance

7 representatives from health care providers
physicians, dentists, pharmacists

6 representatives from public
academia



Process of New Drug Pricing



Similar Drug Method

Price of a new drug is determined

as one day expenditure of the new drug

equivalent to

one day expenditure of the similar drug



Additions to Base Price

- Innovative addition: 70 - 120%
developed with innovative idea
high efficacy or safety
much improvement in treatment of disease
- Useful addition I: 35 - 60%
two of above criteria achieved
- Useful addition II: 5 - 30%
high efficacy or safety OR
much improvement in treatment of disease



Costing Method

No similar drug exist.

Based on costing data submitted by manufacturers.

Fixed proportion is used for cost of R&D, marginal profit and distribution, based on average of pharmaceutical industry.

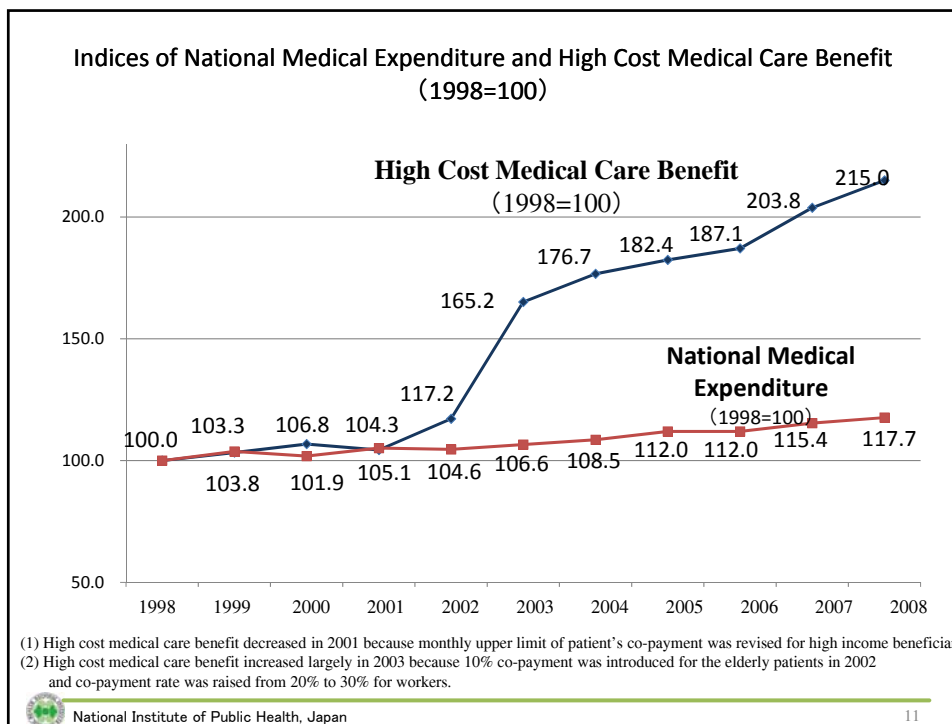
Additional profit rate may be applicable for some innovative products.



Current Issues of Medical Expenditure in Japan

- Increasing expenditure because of not only population ageing but also innovation of new technologies.
- New advanced diagnostic and treatment technologies have been introduced.
- If insurance premiums or tax funding are limited, we have to consider efficient use of health care budget.





Use of Economic Evaluation Data in Japan

From 1992, pharmaceutical companies are allowed to attach the results of economic evaluation to the new drug application dossier. It is not mandatory and there are no guidelines for the methods of study.

For medical devices procedures, approximate cost estimation should be attached.

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Cost Effectiveness Evaluation Committee

In April 2012, a new committee on cost-effectiveness evaluation was established under Chuikyo.

Members of the Committee

- 6 health care insurers
- 6 health care providers
- 4 public
- 4 industry
- 3 experts



Agreed in the Committee in Early Stage

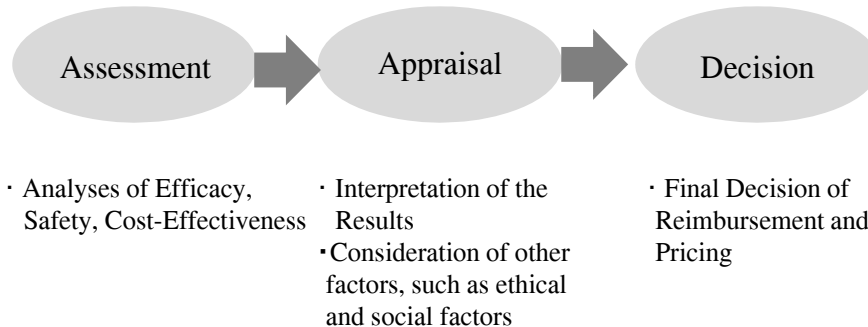
Prioritized technologies to be evaluated

1. Not for rare diseases.
2. Existence of alternative health technology
3. Large financial impact
4. Evidence of efficacy and safety

Reimbursement decision and pricing should not just be based on cost-effectiveness analyses. Other factors must be considered.



Assessment, Appraisal, and Decision-making



Basic Policy on Economic and Fiscal Management and Reform 2015

In addition, it will consider the cost-effectiveness of insurance coverage of medicine and medical devices as a way to cope with the sophistication of healthcare. The government will introduce such cost-effectiveness analysis on a trial basis for the FY2016 revision of remunerations for medical treatment. Subsequently, it will seek to promptly introduce cost-effectiveness analysis on a full-fledged scale.



Pilot Program of Cost Effectiveness Evaluation of Pharmaceuticals and Medical Devices Since April 2016

- Target products
 - △ New products
 - Existing products
- Use of evaluation results
 - × Insurance coverage decision
 - Reimbursement price decision



Two Issues Considered in the Committee

1. Economic evaluation process may take time in addition to the approval process.

As a rule, new drugs are included in the reimbursement drug list within 60 days after approval. It may be difficult to perform the economic evaluation within 60 days. This may cause the delay of coverage.

2. Patients basically will not want to limit access to the new technologies.

If the new technologies are not covered by insurance scheme based on the economic evaluation, it may limit the access to those technologies by patients.



Selection Criteria for Existing Drugs/Medical Devices

Exclusion criteria

- a) Designated rare intractable disease
- b) Request, etc., for the development based on the Review Committee on Unapproved Drugs, etc.

Selection criteria

a) Drugs listed for fiscal years 2012 to 2015, whose price was determined by **similar drug/efficacy method**, with the following criteria.

- i) **The premium rate is the highest.**
- ii) **The expected peak sales is the highest** among drugs for which a premium of 10% or more.

b) Drugs listed for fiscal years 2012 to 2015, whose price was determined by **costing method**, with the following criteria.

- i) **The profit premium rate is the highest.**
- ii) **The expected peak sales is the highest** among the items for which a premium of 10% or more.

* **Including pharmacological analogues** of the drugs selected based on these criteria.



Selected Existing Drugs/Medical Devices

	Drugs (7 items)	Medical Devices (6 items)
similar efficacy (functional category) comparison method	Sofosbuvir	Kawasumi Najuta Thoracic Stent Graft System
	Ledipasvir Acetate/Sofosbuvir	Activa RC
	Ombitasvir Hydrate/ Paritaprevir Hydrate/Ritonavir	Vercise DBS System
	Daclatasvir Hydrochloride	Brio Dual 8 Neurostimulator
	Asunaprevir	
cost calculation method	Nivolumab	J-tec Autologous Cultured Cartilage
	Trastuzumab Emtansine	Sapien XT



Selection Criteria for New Drugs/Medical Devices

Exclusion criteria

- a) Designated rare intractable disease
- b) Request, etc., for the development based on the Review Committee on Unapproved Drugs, etc.

Selection criteria

- a) Drug price will be determined by **similar drug method**, the manufacturer request **a premium rate of 10% or more**, and the **expected sales will be over 50 billion yen for drugs /5 billion yen for medical devices**.
 - b) Drug price will be determined by **costing method**, the manufacturer request **a profit premium of 10% or more**, and the **expected sales will be over 10 billion yen for drugs /1 billion yen for medical devices**.
- Results of evaluation for new products will not be reflected to pricing decision in the pilot program because it will not be able to be evaluated during the 60 days after approval.
 - Drugs and medical devices which will be approved after October 2016 are applicable.



Process of Cost Effectiveness Evaluation of Pharmaceuticals and Medical Devices

Data Submission

The Marketing Authorization Holder will carry out the analysis based on analyses guidelines and submit data of cost effectiveness analyses.

Preliminary consultation about the framework of analysis will be held before the initiation of the analysis.



Review and Re-analyses

Submitted data will be reviewed neutrally by a public organization, in collaboration with external specialists.



Appraisal

At meeting of the **Special Organization for Cost-Effectiveness**, results of analyses provided by the company and the review group, appraisal will be performed from the expert's viewpoint, and a draft of the evaluation will be prepared (undisclosed discussion).

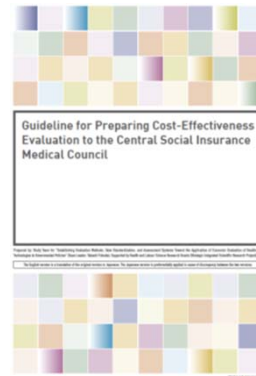
The marketing approval holder who submitted the data can attend the meeting of the Special Organization for Cost-Effectiveness and directly express views at the meeting.



Guidelines for Cost Effectiveness Analyses

- 1 Objectives
- 2 Perspective of analysis
- 3 Target population
- 4 Comparator(s)
- 5 Additional benefit in effectiveness/safety
- 6 Methods of analysis
- 7 Time horizon
- 8 Choice of outcome
- 9 Sources of clinical data
- 10 Calculation of costs
- 11 Long-term care costs and productivity loss
- 12 Discounting
- 13 Modeling
- 14 Uncertainty
- 15 Reporting/publication

Developed by the research group funded by MHLW.



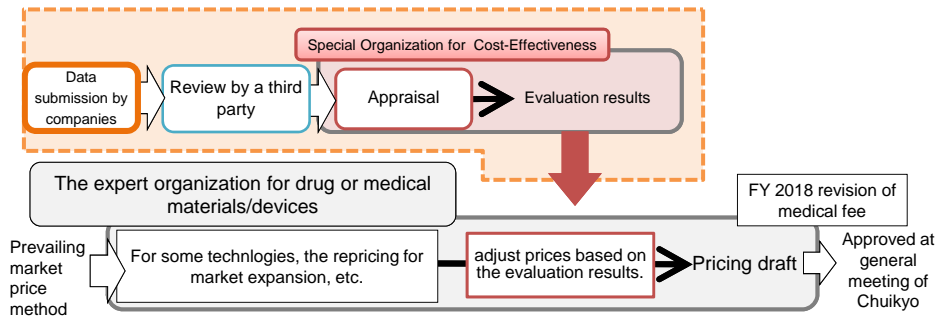
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Process in the Pilot Introduction

- The results of evaluation by the Special Organization for Cost-Effectiveness will be used for price adjustments after the application of existing pricing (re-pricing) rule of drugs and medical materials/devices.
- Concrete methods for price adjustments will be discussed during the process of FY 2018 revision of medical fee.

<Process (summary) in the pilot introduction>



Future Schedule

April 2016 Trial introduction of cost-effectiveness evaluations

- Designation of items subjected to re-pricing and start of the **preparation for data submission by companies**
- Preliminary consultation at the Special Organization for Cost-Effectiveness (by summer)

March 2017 • Deadline for submission of the results of the analysis by companies
• **Start of review by the academic group**

- **Implementation of appraisal** by the Special Organization for Cost-Effectiveness
- **Implementation of price adjustments based on the evaluation results** and preparation of a pricing draft by the expert unit for drug and expert unit for medical materials/devices.

April 2018 Implementation of re-pricing based on the cost-effectiveness evaluations



Issues to be discussed toward full-scale implementation

1. Review of the selection criteria
2. Factors considered in appraisal phase in Japan, from the viewpoints of the ethical and social impacts, etc.
3. Systems required for rapid evaluations, and the quality, contents, etc., of the data to be submitted for new listing technologies
4. Promotion to collecting data for cost-effectiveness evaluation in Japan
5. Application to reimbursement decision-making based on the evaluation results.

