The Pilot HTA Program in Japan

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IP11: A Trial HTA Introduction in Japan: Learning and Way Forward
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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 2014,
Annual Medical Expenditure : JPY 40,807 billion
8.3% of GDP

321,100 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

Special Committee on Cost Effectiveness Evaluation

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
  2 experts

Basic Policy on Economic and Fiscal Management and Reform 2015 (JAPAN)

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

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

Cultural/Institutional Background to Coverage/Pricing Decision of Pharmaceuticals

1. Almost all prescription drugs are covered by health insurance scheme.
2. All the drugs have their reimbursement prices determined at the Central Social Insurance Medical Council (Chu-I-Kyo).
3. There exist pricing rules for new drugs.
4. Coverage/pricing decision should be made within 60days (90 days maximum).
5. Those prices are revised every two years based on the repricing rules.

Two Issues Considered in the Commitee

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 to be evaluated

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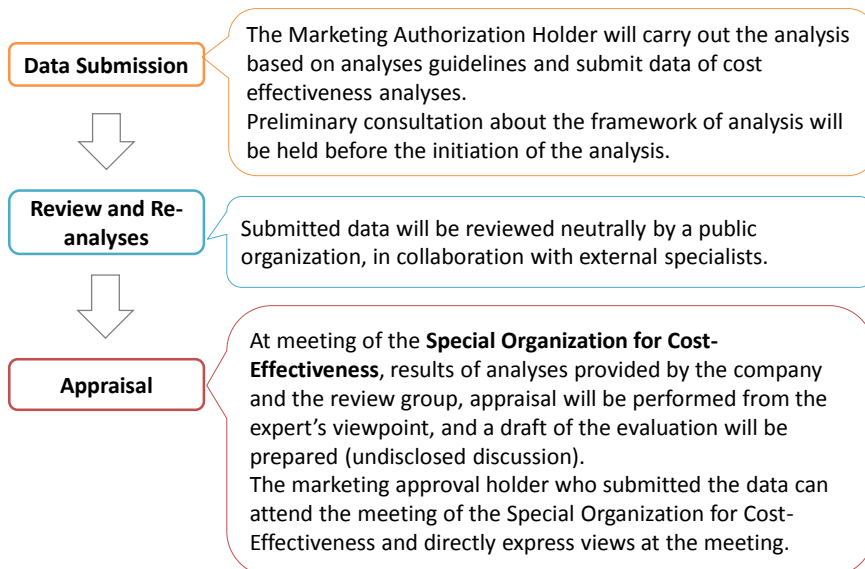
Selection criteria

a)Drugs listed for fiscal years 2012 to 2015, whose price was determined by **similar drug 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.

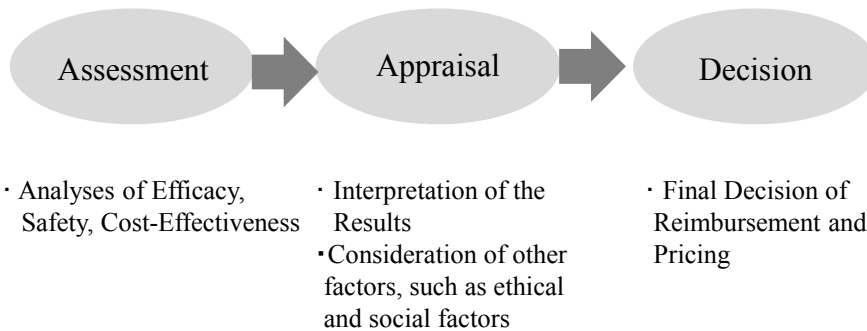 * **Including pharmacological analogues** of the drugs selected based on these criteria.

Selected Existing Drugs/Medical Devices

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

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.

Assessment, Appraisal, and Decision-making

Assessment → Appraisal → Decision

· Analyses of Efficacy, Safety, Cost-Effectiveness

· Interpretation of the Results
· Consideration of other factors, such as ethical and social factors

· Final Decision of Reimbursement and Pricing

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.

Guideline for Preparing Cost-Effectiveness Evaluation to the Central Social Insurance Medical Council

Perspective of the Analysis

"Public healthcare payer's perspective" is a standard perspective that pertains to factors such as costs, comparators, and target populations within the range of the public health insurance system in Japan.

If the effect on long-term care costs is important with regard to a healthcare technology, it is acceptable to perform an analysis from the "public healthcare and long term care payer's perspective."

If the introduction of a technology has a direct influence on productivity, it is acceptable to perform an analysis that considers broader costs and counts productivity loss as a cost.

Choice of Outcomes

The quality-adjusted life year (QALY) should be used as a basic outcome unit. Other outcome units can be used depending on the characteristics of the illnesses, drugs, and/or medical devices.

When QALY is calculated, the QOL score should be reflective of the value for a general population using questionnaires (EQ-5D, SF-6D, HUI, etc.), the standard gamble (SG) method, and the time trade-off (TTO) method.
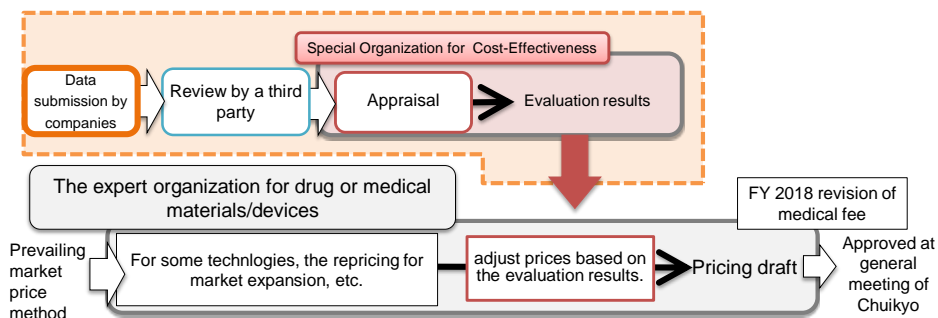
Process in the Pilot Program

➢ 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>

Price Adjustment in the Pilot Program (overview)

○ Repricing is conducted based on the repricing rate corresponding to ICER
  ・ ICER < 5 million JPY   ⇒ No change
  ・ 5 million JPY < ICER < 10 million JPY   ⇒ Price reduction based on ICER
  ・ ICER > 10 million JPY   ⇒ Price reduction with maximum reduction rate

○ Price increase is conducted for cost-saving items
  ※ Up to 50% increase of premium (within 10% of overall price)

【Determination of repricing rate】

【Repricing scope】

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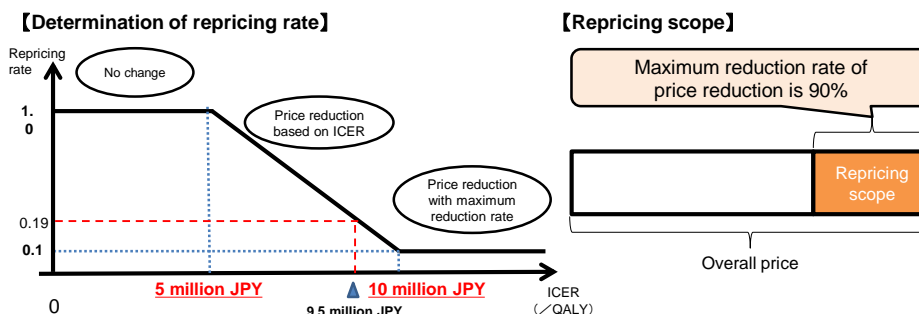
Discrepancy of Analysis Results

○　In 7 items of the 13 items targeted for trial adoption, analysis results submitted by company and reanalysis group were markedly different.
○　It was mainly due to the following reasons, and the technical problems were revealed.

【**Major reasons for the discrepancy of analysis results**】
○　Difference of the scope (analysis framework)
　　・(e.g.) Target population, Method of intervention, Comparator

○　Difference in the selection criteria of the data used in analysis
　　・(e.g. 1) Data used for " effect estimation"：
　　　Depending on the priority setting (i.e. statistical reliability, newness of data), the selected data is different, hence the estimated effect will be different.
　　・(e.g. 2) Data used for "cost estimation"：
　　　Depending on the differences of the data set or definition of the target patients group, the estimated cost will be different.

Verification of 7 items・・Dealing with Technical Problems

○ In order to consider a more rational analysis method, the items where the analysis results of the company and the third party greatly differed were continued the verification (analysis as a verification) (until 2018). Repricing conducted again based on this result.

①**Participation of clinical experts**	○　A working group (WG) for each field of the targeted items consisting of clinical experts in the field and experts on health economic is established under the expert organization. ○　Considering opinions from companies, the WG discusses how to analyze and evaluate. Based on the results, the expert organization discusses the analysis framework and summarize the analysis results.
②**Preliminary consultation on analysis and evaluation**	○　Prior to the analysis, the expert organization discusses and decides the framework of analysis for each items considering opinions from companies and the WG. In principle, analysis is conducted in line with the framework. ○　As for the 7 items to be verified, since they were analyzed by company and reanalysis group last year, the issues for analyzing each item have already been clear to a certain extent. Therefore, in principle, the analysis was conducted by the experts.
③**Clarification of analysis method**	○　In this verification, in line with the analysis guidelines, the aim is to analyze considering characteristics of each item by clarifying the operation method of the guideline for each item in the WG and the expert organization.

Issues to be discussed toward full-scale implementation

（1）Selection
　・Scope of target medical technologies
　・Selection criteria（premium、market size etc.）
　・Exclusion criteria
　・Selection timing
　・Process of selection and public announcement
　　etc.

（2）Submission by company
　・Preliminary consultation
　・Setting of standard time period for company submission
　・Concept of analysis guideline
　・Involvement of the Cost-effectiveness Evaluation Expert
　　Organization etc.
　　etc.

（3）Reanalysis
　・Setting of standard time period for reanalysis
　・Establishment of a highly transparent organization and system
　　from a third-party perspective
　・Involvement of the Cost-effectiveness Evaluation Expert
　　Organization etc.
　　etc.

（4）Appraisal
　・Verification method from a scientific perspective
　・Ethical and social consideration factors
　・Method of summarizing evaluation results
　・Method of reporting and publication of evaluation results
　・Establishment of a highly transparent organization and
　　system from a third-party perspective
　　etc.

（5）Repricing
　・Repricing scope
　・Repricing rate
　・Setting of reference value for repricing (including willingness
　　to pay survey)
　・Repricing coefficient
　・Timing of repricing
　　etc.