Current status and challenges for medical economic evaluation of cancer care in Asia

How can we mobilise action to realise UHC in Asia?
World Cancer Congress in Paris, 2016.11.2

Takashi Fukuda, PhD
National Institute of Public Health, Japan
New Technologies and Medical Expenditure in Asia

• Medical expenditure is increasing even in Asian countries.
• 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.
Health Technology Assessment in Asia

• Some Asian countries started Health Technology Assessment Program, especially use of economic evaluation for new drugs and procedures, in order to consider cost effectiveness of new treatments.
Health Technology Assessment in Asia

• Thailand
  – HITAP (Health Intervention and Technology Assessment Program) established in 2007 under the Ministry of Public Health
  – Evaluates pharmaceuticals, medical devices, interventions, individual and community health promotion, and disease prevention

• Taiwan
  – HTA program started in CDE (Center for Drug Evaluation) in 2008 -> NIHTA from 2013
  – assist the National Health Insurance Administration of the Ministry of Health and Welfare in performing effectiveness and economic assessments on new drugs and new medical devices

• South Korea
  – Mandatory of economic evaluation data for new drugs from 2008
  – HIRA (Health Insurance Review and Assessment Service) makes decision for reimbursement.
## Reimbursement Decision of Oncology Drugs based on HTA in South Korea (example)

<table>
<thead>
<tr>
<th>DRUG</th>
<th>NAME</th>
<th>INDICATION</th>
<th>DECISION</th>
<th>JAPAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cetuximab</td>
<td>Erbitux</td>
<td>Colorectal cancer</td>
<td>Rejection</td>
<td>Reimbursable</td>
</tr>
<tr>
<td>Fulvestrant</td>
<td>Faslodex</td>
<td>Metastatic breast cancer</td>
<td>Rejection</td>
<td>Reimbursable</td>
</tr>
<tr>
<td>Nilotinib</td>
<td>Tasigna</td>
<td>CML</td>
<td>Conditional approval</td>
<td>Reimbursable</td>
</tr>
<tr>
<td>Lapatinib ditsylate</td>
<td>Tykerb</td>
<td>HER-2-positive breast cancer</td>
<td>Approval</td>
<td>Reimbursable</td>
</tr>
</tbody>
</table>

Health Technology Assessment in Japan

In April 2012, a new committee on cost-effectiveness evaluation was established under the Central Social Insurance Medical Council, where the reimbursement and pricing decision are made.

Members of the Committee
- 6 health care insurers
- 6 health care providers
- 4 public
- 4 industry
- 3 experts
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 in Japan 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 60 days (90 days maximum).
5. Those prices are revised every two years based on the repricing rules.
Process of New Drug Pricing

- **Similar drug exist?**
  - Yes → **Similar drug method**
    - Additions
    - Innovative
    - Useful
    - Market size
    - Children use
  - No → **Costing method**

- **Foreign Price Adjustment**
  - (US, UK, Germany, France)
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

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

<table>
<thead>
<tr>
<th>Drugs (Name)</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir (Sovaldi)</td>
<td>Chronic hepatitis C infection</td>
</tr>
<tr>
<td>Ledipasvir Acetonate/Sofosbuvir (Harvoni)</td>
<td></td>
</tr>
<tr>
<td>Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir (Viekirax)</td>
<td></td>
</tr>
<tr>
<td>Daclatasvir Hydrochloride (Daklinza)</td>
<td></td>
</tr>
<tr>
<td>Asunaprevir (Sunvepra)</td>
<td></td>
</tr>
<tr>
<td>Nivolumab (Opdivo)</td>
<td>Melanoma, etc.</td>
</tr>
<tr>
<td>Trastuzumab Emtansine (Kadcyla)</td>
<td>HER2-positive metastatic breast cancer</td>
</tr>
</tbody>
</table>
Selection Criteria for New Drugs

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.

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.
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>

Data submission by companies

Review by a third party

Appraisal

Evaluation results

The expert organization for drug or medical materials/devices

For some technologies, the repricing for market expansion, etc.

Adjust prices based on the evaluation results.

Pricing draft

Approved at general meeting of Chuikyo

Prevailing market price method

FY 2018 revision of medical fee
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.
Thank you.