ISPOR Asia Pacific 2018, Tokyo, Japan
10 September 2018

W5: Japanese HTA and Pricing: Current Methods and Future Potential

Introduction of Japanese Pricing System

Makoto Kobayashi, MEng, PhD
Director and COO
CRECON Medical Assessment Inc., Tokyo, Japan
kobamako@crecon.co.jp

Overview of health care system in Japan

Characteristics	Descriptions
Universal health insurance	• The whole nation is guaranteed by public health insurance. • This program is based on social insurance system, but public budget is invested as well in order to maintain it.
Copayment	• Patient copayment is basically 30% of the total treatment cost • When a patient's monthly medical payment reaches a certain limit, approx. JPY80,000 / month ($720/month), the excess is refundable (High-cost medical care expense benefit)

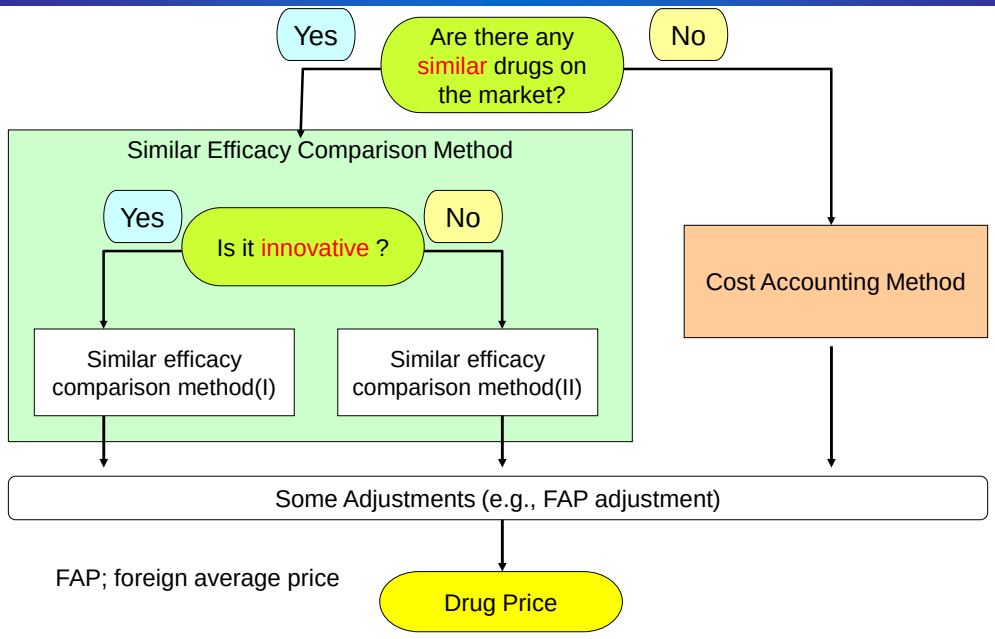
Overview of current drug pricing system in Japan

- Drugs must be covered by NHI Drug Price standard to be used in insurance-covered healthcare
- NHI Drug Price Standard is:
  - an item list in which usable drugs in insurance-covered healthcare are specified
  - a price table which specifies prices which can be reimbursed in insurance-covered healthcare
- Timing of listing of new drugs:
  - 4 times per year for new drugs (Feb, May, Aug, Nov)
  - within 60 days after marketing approval in principle, within 90 days at the latest
- After listing, drug prices are periodically revised based on official survey of the actual sales price (market price) to medical institutions and pharmacies

I will focus on pricing for new drugs in this presentation

3

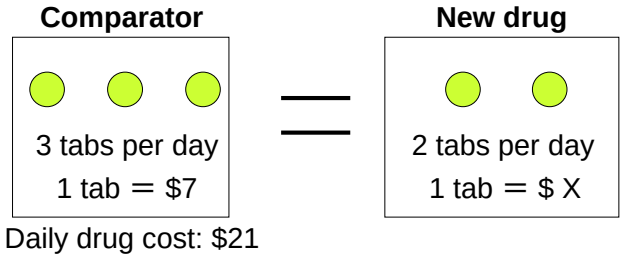
Pricing methods for new drugs in Japan



4

Similar efficacy comparison method

- Comparator = Most similar drug on market
- Daily cost(new drug) = Daily cost(comparator)



Daily drug cost: $21

Price of new drug($X) ＝($7 × 3 tabs)／2 tabs ＝ $10.5

- ***Premium*** can be added depending on novelty.

Premium rates

- When there is a comparable drug with same indication in the list, the daily price of a new drug is determined so that it is same as the daily cost of the comparable drug.
- Premiums below are applied when the new drug is proven to be highly useful.

Premium	Rate	Descriptions
Innovation premium	70 - 120%	New mechanism of action, high efficacy or safety, and significant improvement in treatment
Usefulness premium	5 - 30%, 35 - 60%	High efficacy or safety, significant improvement treatment
Marketability premium	5%、10～20%	Orphan drugs, etc.
Children premium	5～20%	Pediatric indication/dosage/administration shown explicitly, etc.
SAKIGAKE premium	10～20%	Premium for products which were designated as target of SAKIGAKE designation

SAKIGAKE Designation System: promoting R&D in Japan aiming at early practical application for innovative pharmaceutical products, medical devices, and regenerative medicines. –"SAKIGAKE" means "taking the lead [initiative],"

Requirements for applying premiums (Innovation premium)

- Innovation premium (rate: 70-120%)
  - Applied to new drugs that meet *ALL* of the following requirements:
    1. The new drug has clinically useful new mechanism of action.
    2. It is objectively shown that the new drug has greater efficacy and safety than existing drugs in the same category.
    3. It is objectively shown that the new drug improves treatment of the disease or trauma indicated for the new drug.

7

Requirements for applying premiums (Usefulness premium)

- Usefulness I premium (35-60%)
  - Applied to new drugs that meet *TWO* of the three requirements for premium for innovation.
- Usefulness II premium (5-30%)
  - Applied to new drugs that meet *ONE* of the following requirements :
    1. The new drug has clinical useful new mechanism of action.
    2. It is objectively shown that the new drug has greater efficacy and safety than existing drugs in the same category.
    3. It is objectively shown that the new drug improves treatment of the disease or trauma indicated for the new drug.
    4. It is objectively shown that the drug offers, as a result of formulation improvement, greater therapeutic usefulness than other drugs in the same category.

8

Cost accounting method

- When there is no comparable drug with same indication in the list, the drug price is determined by the *Cost Accounting Method*.

Cost items	Descriptions
Manufacturing cost	Cost of raw materials, labour cost, Manufacturing expenses
Selling expenses, research expenses	Cost of activities to supply information about adequate drug use, general control cost, research and development cost, PMS cost, etc.
Operating income	Average operating income : 14.7%
Marketing cost	Calculated using a fixed rate of wholesaler
Consumption tax	Consumption tax and local consumption tax (8% of the total cost above)

9

Premium for CAM

- Premiums below are applied when the new drug is proven to be highly useful (same as SECM).
- Premium is adjusted by a coefficient which is defined based on the extent of disclosure of cost information by the company (coefficient of disclosure)

Premiums	Rates
Innovation premium	70 - 120%
Usefulness premium	5 - 30%, 35 - 60%
Marketability premium	5%、10～20%
Children premium	5～20%
Sakigake designation scheme premium	10～20%

Example of premium calculation

Accumulated cost : 100 yen

Innovation premium : 100 %
Coefficient of disclosure :0.5

Premium added: 100 yen x 100% x 0.5 = 50 yen

10

Example of similar efficacy comparison method - Sofosbuvir (SOVALDI®) -

- SOVALDI® 400mg tablet was compared with the 3 comparable drugs below.
- Innovation premium was applied because it was proven to be more effective than the others.

	400mg teblet	Descriptions
Comparable drug	Telaprevir (TELAVIC® 250mg tablet)	1,429.60 yen（12,866.40yen）*
	Peginterferon Alfa-2b (PEGINTRON® powder for injection 100μg/0.5mL)	30,332yen（4,333yen）*
	Ribavirin (REBETOL® 200mg hard capsule)	627.60yen（2,510.40yen）*
Premium	Innovation premium（100%）	Before：23,396.70 yen After：46,793.40 yen
Adjustment with foreign prices	Before：46,793.40 yen After：61,799.30 yen	Foreign average price: 92,402.90yen
Determined price	**61,799.30 yen（61,799.30 yen）* ($561)**	

*drug price（daily drug price）

11

Example of cost calculation method - Olaparib (Lynparza®) -

- The costs below were added up to the manufacturing cost of Lynparza® 100mg tablet and the drug price was calculated.

	100mg vial	Descriptions
Manufacturing cost	2,896.70 yen	-
Operating income	499.20 yen	14.7% of the price without the distribution cost
Marketing cost	267.40 yen	7.3% of the price without the consumption tax
Consumption tax	293.10 yen	8% of the total price above
Premium	39.60 yen	Premium for usefulness(II): 5% Coefficient: 0.2
Determined price	**3,996.00 yen ($36)**	

12

Premium in pricing

- Acquiring higher premium is very important for Japanese drug pricing system for new drugs

However,,,,,

13

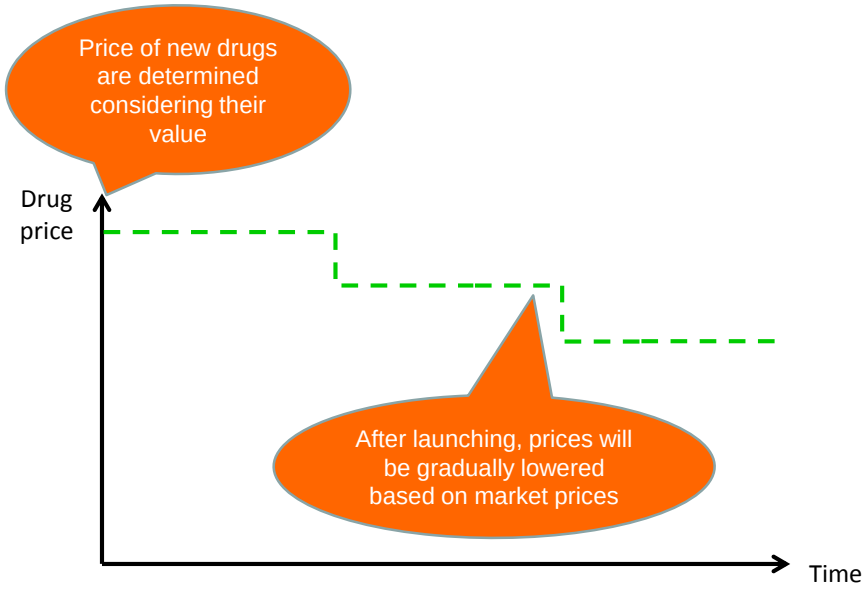
Chance of winning premiums

	No. of drugs (1997 - 2017)
Total no. of listed drugs	893
CAM	206
SECM	630
Premium	
Innovation	3 (0.3%)
usefulness I	18 (2.0%)
usefulness II	128 (14.3%)

CAM: cost accounting method
SECM: similar efficacy comparison method

14

Principle of pricing system in Japan



15

Conclusions

- Premiums are playing an important role in the pricing system for new drugs in Japan
- Acquiring higher premium, such as "Innovation Premium" is tough challenge for companies
- The pilot Japanese HTA was conducted for existing products but companies can submit cost-effectiveness data when submitting an application of new price.
- The evidence of cost-effectiveness can paly an important role when companies claims that the higher premium is reasonable for their product

16

17

Change in Premiums

Premium rates haven't changed for 10 years

Premiums	Before	FY2002	FY2006	FY2008	FY2018
Innovation (%)	40	40 - 100	50 - 100	70 - 120	70 - 120
Usefulness I (%)	10	15 - 30	25 - 40	35 - 60	35 - 60
Usefulness II (%)	3	5 - 10	5 - 20	5 - 30	5 - 30

18