

Update on HTA in Japan: critical appraisal on the methods

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New HTA in Japan

- Cost-benefit is implicitly reflected into pricing of drugs and devices (quasi-VBP).
- Submission of economic evidence to Central Social Insurance Medical Council (CMC) has been historically recommended for new drug/device application since early 90's.
- As a pilot policy, explicit cost-effectiveness evidence, i.e., ICER, became required for selected drugs/devices in April 2016.
- Purpose: to address public concerns about soaring healthcare costs,

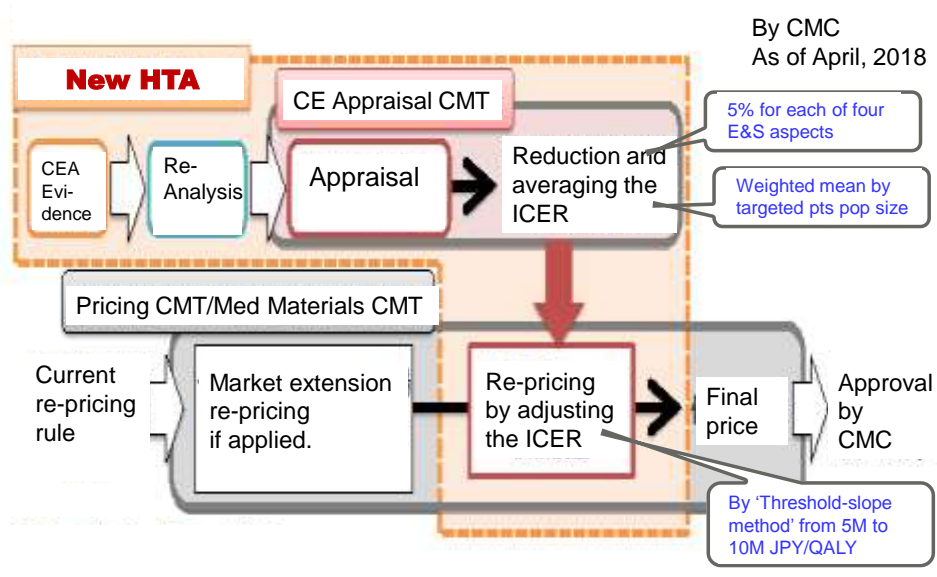
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Targeted product

- Drugs/devices with high budget impact, and adjusting the price according to the cost-effectiveness:
- Seven existing drugs (5 HCV drugs, 2 oncology drugs) and six devices (2 for CV surgery, 3 for tremor, 1 for trauma surgery) were selected as pilot targets in 2016, and the adjusted price came into operation in April 2018.
- Two new drugs (oncology) and two devices (CV surgery) were selected and their pharmacoeconomic review is currently in progress.
- Drugs for orphan diseases (e.g., specified diseases, hemophilia and HIV), and products requested from unmet medical needs committees

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Decision processes for re-pricing adjustment



The Appraisal Committee

- Scientific validity: comply to the CMC methodology guideline.
- Ethical and social aspects : Four aspects
 - **Public health benefits**: infection control providing a population with public benefit, not just for an individual patient.
 - **Significant improvement in cost-effectiveness beyond the perspective of UHC**: including nursing care and productivity loss.
 - **Not much change of QOL, but improvement of survival in serious illnesses**: cancer tx.
 - **Innovative therapy for rare and incurable illness without any alternative therapy.**
- Reduction of ICER with 5% for each ethical/social aspect --- No scientific rationale of reduction (bonus?) and why 5% even if reduction is justified.

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Weighted average of ICERs

- Averaging out ICERs for different indications proportional to patient-population size of each indication, ignoring different comparators
 - Difficult to properly interpret (What does the average of ICERs mean?)
 - Averaging out cost and benefit, respectively, would be better.
- On Aug 22, the CMC suggested this method will be changed into estimating the weighted average after each price adjustment for each ICER is conducted. That is, change averaging of ICERs first into pricing of each ICER first.
- However, it cannot be a scientifically sound solution of the problem.

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Table 2. Example of disparity between two estimates of weighted average.

	ΔC	ΔE	ICER	Weight	ICER \times Weight	$\Delta C \times$ Weight	$\Delta E \times$ Weight
	1600	2	800	0.7	①560	1120	1.4
	2000	5	400	0.3	②120	600	1.5
						③1720	④2.9
Weighted Average					①+② =680		③÷④ =593
					An estimate By CSIMC		Another Estimate

Re-pricing adjustment

Price Adjustment Formulae

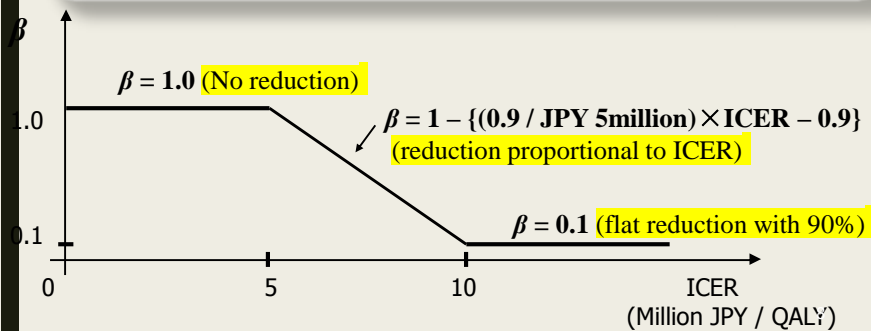
#1 Similar efficacy method (SEM):

$$\text{Adjusted price} = \text{Current price} - \text{Premium portion} \times (1 - \beta).$$

#2 Cost calculation method (CCM):

$$\text{Adjusted price} = \text{Current price} - \text{Premium portion} \times K \times (1 - \beta).$$

β : adjustment coefficient, K: adjustment due to sales profit



Re-pricing adjustment

- ‘Threshold-slope’ method: automatically determine revised price according to an estimate of ICER.
- too algorithmic (No room for Appraisal Committee members to discuss)
- No scientific rationale: The “Threshold and slope” curve is arbitrary.
- Contradiction to WHO’s objection to VBP (ICER-based pricing is an extreme form of VBP)
- No space to consider deliberative decision making
- It excludes alternative methods (rebate, reward rules, etc.)
- WTP threshold in UK is set for coverage decision, not for pricing.
- No consideration of MCDA which is a key to integrate multiple factors with wider concept of value.
- Incentive for promoting innovation with large number of ICER has not been well addressed.

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Viewpoint of WHO

- VBP does not take into account affordability and total cost.
- If used in isolation (such as ICER-based pricing in Japan), it also has the potential to exclude other valuable price-negotiation tools such as tendering and price-volume agreements.
- If VBP is used to justify to extract the full WTP (or over WTP threshold in Japanese context) of the consumer, it also results in all the surplus being distributed to the producer rather than also being distributed to the consumer.

Source:

- FAIR PRICING FORUM 2017 MEETING REPORT, Amsterdam, The Netherlands, 11 May 2017
- Fair Pricing Forum, Informal Advisory Group Meeting in WHO, Geneva, 22-24 Nov 2016

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Other problems

- Appraisal Committee: No transparency
- Insufficient stakeholders engagement, including patient engagement
- No discussions in depth on the occasion of hearing from company
- No negotiation between CMC and company
- Capacity to conduct re-analysis and appraisal in CMC within 60 days is very limited so far. (Capacity building is a pressing task)

Brief conclusion

- Japan stepped into a quite ambitious challenge for ICER-based pricing.
- The methodology still suffers from scientific turmoil.
- No roadmap/prescription to attain the final goal: Everybody says affordability and sustainability of the Japanese UHC system is important, but no one knows how we could make it.