Post-approval hurdles: Differences and strategies between Japanese and the U.S. reimbursement systems

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Overview of healthcare system of two countries

	Japan	USA
Health insurance		
Payer	(substantially) Single	Multiple
Government or private	Government (private company provides supplemental coverage)	Government and private (government provides plans for aged, disabled, low-income)
FFS or lump-sum payment	Mainly FFS (FFS for medical devices)	Mainly lump-sum (lump-sum for medical devices)
Health provision		
Number of hospital (2021)	8,205 (hosp/15,000 people) Private-Public: 80%-20%	6,129 (hosp/54,000 people) Private-Public: 80%-20%
Centralization	Fragmented (85% of hospitals operate on fewer than 30 cases of artificial hips per year)	Centralized

(From this page onward, a comparison of the Japanese NHI and U.S. Medicare will be made)

Process to reimbursement coverage (new devices)

		Japan	USA
New Devices/ categories	Application process	- C1/C2/B3 - Challenge application	- CPT code - National Coverage Determination (NCD) process by CMS + Local decision
	Duration from reg approval to coverage	0.8 years (ave) * (timeclock is 5-6 months after the dossier is received)	5.7 years (median)** (2-3 years per hearing from companies)
	# of subjects	20-30/year	-8/year
	Agency	MHLW	CMS
Similar to existing products/categories	Application	A1/A2/A3/B1/B2	Coverage Dossier
	Period to coverage	-30days (A1/A2/B1) -4 months (A3/B2)	Few weeks to few months
	# of subjects	Several thousands	Several thousands ?
	Agency	MHLW	MACs

*Tamura, et al. (2018): Reimbursement pricing for new medical devices in Japan. Int J Health Plann Mgmt. 2018;1–11.
**Sexton, et al (2023): Time From Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies. JAMA Health Forum. 2023;4(8):e232260
Note1: CED:Coverage Evidence Development), NTAP: New Technology Add-on Payment)
Note2. In Japen, reimbursement price of existing products are adjusted based on market price and foreign price. In US, DGR cost is changed based on hospital cost survey

Evaluation classification of insured medical materials in Japan

Procedural fee

A1 (Package)
Comprehensive evaluation of existing medical fee items (e.g., sutures, IV needles for blood collection)
A2 (specified package)
Comprehensive evaluation on existing specific medical fee items (e.g., ultrasound equipment and tests)
A3 (existing technology, modified)
Evaluation on technology that uses the product in existing medical fee items (with changes on important points)

Device fee

B1 (existing functional classification)
Evaluation by the existing functional classification, separately from the technical fee (e.g., coronary stent, pacemaker)
B2 (existing functional classification, modified)
Evaluation by the existing functional classification, separately from the technical fee (with changes in the definition, etc. of functional classification)

B3 (premium for improvement with due date)
Evaluation by adding premium for improvement with due date to the existing functional classification

→ Evaluation classification requiring consent of Chuikyo (create a new code/category)

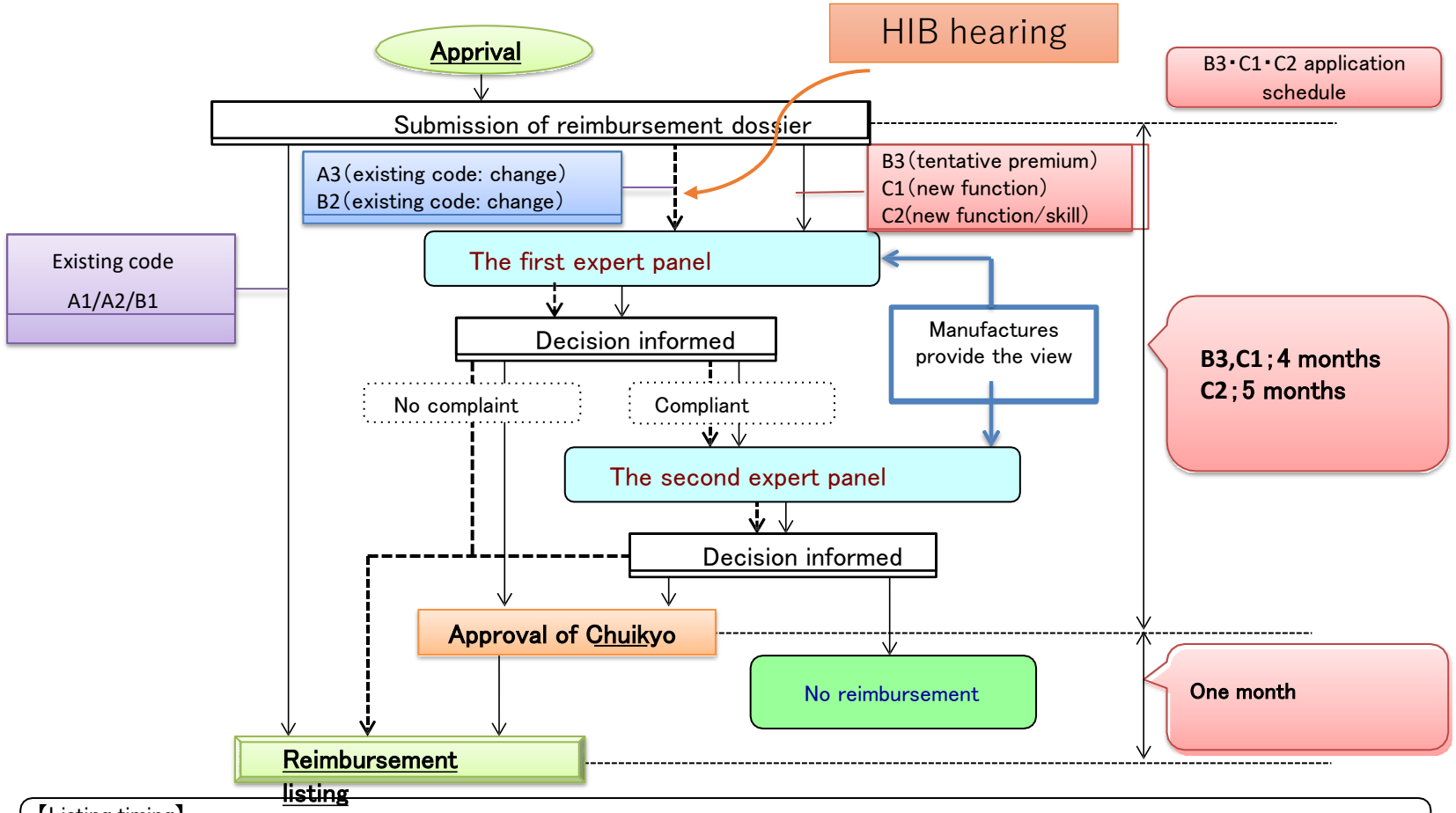
C1 (new function)
Require a new functional classification, and technologies using them have already been evaluated
(Example: Artificial joint with special processing)

C2 (new function/new technology)
Require a new functional classification, and technologies using them have not been evaluated
(Example: Lead-free pacemaker)

R (remanufacturing)
Evaluation of remanufactured products by new functional classification

F Medical devices not adaptable to insurance coverage

Flow of device reimbursement listing in Japan



【Listing timing】

A1 ： 20 days after dossier submission (approval day in case of inclusion listing products)

A2・B1 ：The first day of each month if dossier is submitted by 10th of prior month

A3・B2： The first day of each month if the decision is made by 10th of prior month

C１・C２・B３：Four times per year（**March、 June 、 Sep、 Dec)**

National Coverage Determination (NCD) process

A procedure undertaken by the Centers for Medicare & Medicaid Services (CMS) to determine the coverage of specific medical procedures, services, or devices under Medicare on a national scale

Process

1.Initiation: An NCD request can be initiated by CMS or an external requestor.

2.Public Comment Period: Once an NCD is opened, CMS allows for a public comment period

3.Evidence Review: CMS reviews all submitted evidence, including clinical trial data, scientific literature, and input from experts.

4.Draft Decision: CMS issues a draft decision memo outlining their proposed coverage decision, followed by another public comment period.

5.Final Decision

6.Implementation: If the decision is favorable, CMS instructs MACs to cover the service or device according to the guidelines set in the NCD.

Applications

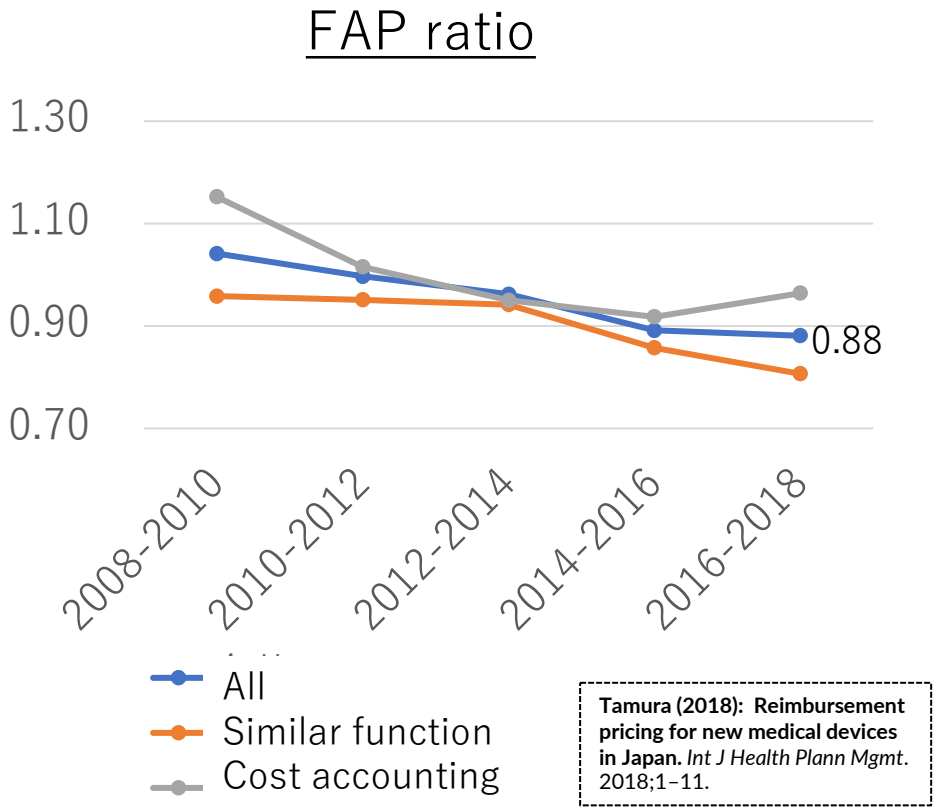
- ✓ Medical Necessity
- ✓ Clinical evidence
- ✓ Detailed information about the medical service or device, including its intended use, mechanism of action, and comparison with existing treatments.

NTAP(New Technology Add-on Payment)

- ✓ designed for high-cost technologies that represent a substantial clinical improvement when the cost of new technology is higher existing treatments
- ✓ add-on codes/payments are typically temporary—lasting about 3 years when granted

Evaluation of innovation

- In the 1990s, the reimbursement prices for medical devices in Japan were significantly higher than those in the US.
- However, recent changes in Japan's pricing, particularly due to policies implemented by MHLW, including the Foreign Average Price (FAP) rule, have resulted in prices that are lower than those in foreign countries, especially the US.



Tamura (2018): Reimbursement pricing for new medical devices in Japan. *Int J Health Plann Mgmt*. 2018;1–11.

Price comparison between US and Japan

(Japanese yen)

	Endotracheal valve	Pacemaker Extraction Catheter	Thrombectomy catheter	Stent Graft
US	330,980	910,000	520,648	2,772,484
Japan	313,000	434,000	448,000	1,490,000
Ratio (Japan /US)	0.95	0.48	0.86	0.54

- These four products are newly reimbursed in September and December in 2023
- US number are list prices submitted by manufactures. Japan number is NHI reimbursement price.

Summary

- The duration from regulatory approval to reimbursement coverage is shorter in Japan compared US. Conversely, reimbursement prices tend to be higher in the U.S.

- Both countries face the challenge of insufficient clinical data when determining reimbursement prices.
  - In the U.S., specific regulations like NTAP, CED, and the potential introduction of TCET (Transitional Coverage of Emerging Technologies) next year, address this issue.
  - In Japan, initiatives such as the "improved premium" and "challenge applications" have been introduced to tackle similar challenges.