Japan

Market Access & Reimbursement in Japan

Avania

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ADVANCING YOUR MEDICAL TECHNOLOGY

Background on the Japanese Reimbursement System

ひと、くらし、みらいのために
厚生労働省
Ministry of Health, Labour and Welfare

- The Japanese government is the main payer for 70% of healthcare goods and services purchased at hospitals, clinics, or prescription pharmacies in Japan.
- Patients are required to pay a co-payment of 30% of the total cost out of pocket.
  - However, if the patient burden exceeds a certain upper limit, the government will provide a subsidy to cover the remaining amount. The upper limit varies depending on an individual's annual income.
- The Ministry of Health, Labor, and Welfare (MHLW) determines coverage policies and pricing while the Ministry of Finance supports the yearly budget allocation.
- Pricing for most devices and / or technology is established by the Central Social Insurance Medical Council (Chuikyo), a separate body associated with the MHLW, following the review by the Insurance Bureau of MHLW.
- The Chuikyo consists of 20 members from academia and various interest groups, including the all-physician Japanese Medical Association, the Japan Pharmaceutical Association, the Japan Medical Device Association and the Japan Federation of Economic Organization.
- There are three Social Insurance Committees under Japanese Medical Association:
  - Gaihoren (Surgical Societies of Social Insurance Committee);
  - Naihoren (Internal Medicine Societies of Social Insurance Committee); and
  - Kanhoren (Nursing Societies of Social Insurance Committee).
- **These committees can place pressure on the MHLW to approve and assess the technical fees for already existing and approved procedures.**

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Key Agencies in Japanese Market Access and Reimbursement.

Agency	Abbreviation	Description
Ministry of Health, Labor, and Welfare	MHLW	Central government ministry responsible for health, welfare, and labor policies in Japan.
Central Social Insurance Medical Council	Chuikyo	Key advisory body that recommends policies to the Minister of Health on health insurance and medical fees, including the reimbursement prices for drugs and medical devices
Japanese Medical Association	JMA	Professional organization for physicians in Japan that advocates for quality healthcare, public health policies, and physicians' rights
Pharmaceuticals and Medical Devices Agency	PMDA	Government regulatory agency responsible for evaluating new drug and medical device applications, post-market safety, and addressing damages related to adverse health effects
Health Insurance Bureau	HIB	Oversees the country's universal health insurance system by planning and establishing insurance programs, including those for employees, the public, and the elderly

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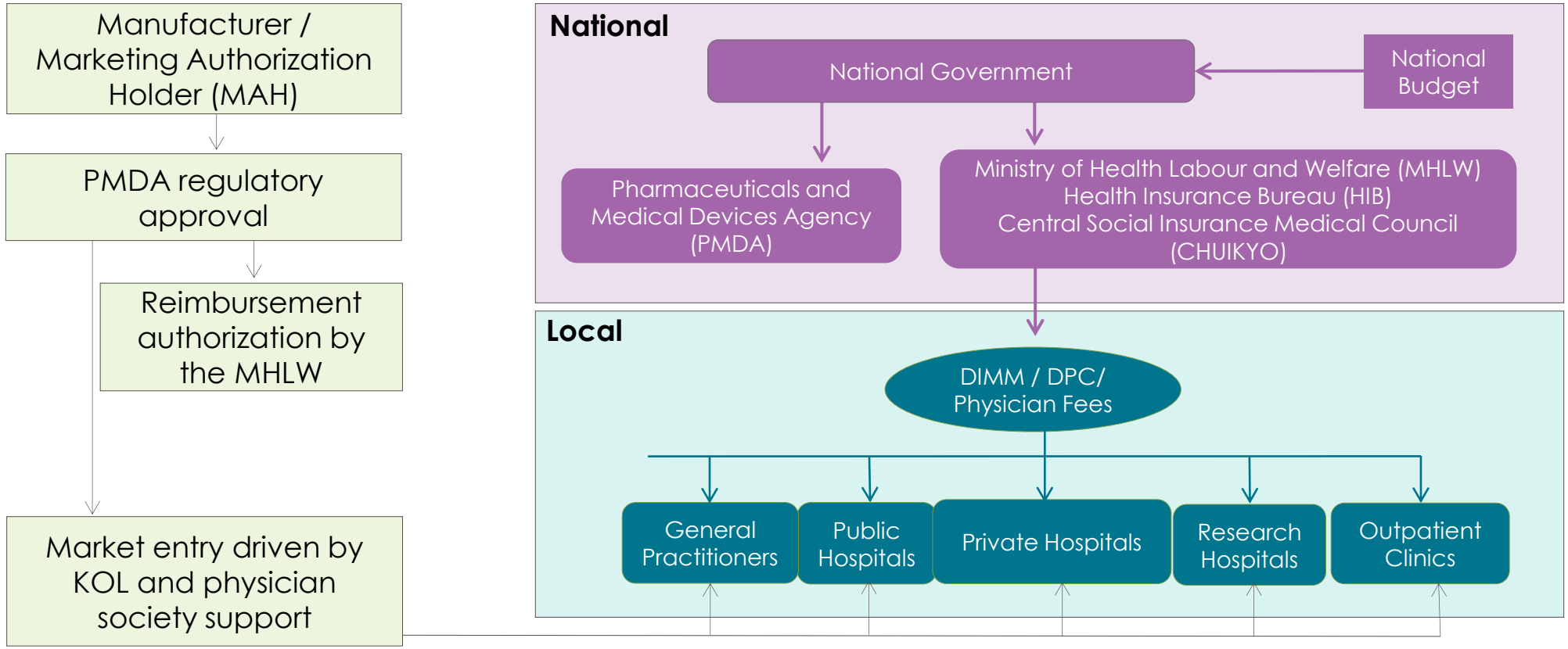
Overview of Japan's medical device pathway.

- Japan has a compulsory social health insurance system, financed by employer contribution, payroll deductions, taxes, and patient co-payments.
- The MHLW is the agency charged with assigning reimbursement under the advice of CHUIKYO and the advisory council.



Reimbursement for medical devices in Japan is determined by the MHLW through two distinct pathways.

Professional Technical Service Fee		Authorized Cost of Disposable or One-Time-Use Medical Devices
• Every medical and surgical procedure, treatment, and diagnosis is paid for at an authorized fixed amount, which includes: — Personnel; — Utility; — Capital equipment amortization; — Inpatient drugs; and — Minor med-surg. supplies. • **Often, even one-time-use medical devices are included in this service fee.**	+	• Major disposable or one-time-use medical devices, such as catheters and orthopedic implants, are assigned a reimbursement price by functional group, and not by brand. • Listed in a fee schedule of Designated Insured Medical Materials (DIMM).

- In the last few years, the MHLW has started providing a comprehensive technical service fee for technologies, wherein the costs of disposable devices are incorporated into a single payment.

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Reimbursement for most medical devices depends on functional category assignment.

- Under the current functional category system of reimbursement for Special Treatment Material (STM)*, the MHLW assigns medical device products to one of the following categories:

	Category		Description
Device Costs are Bundled	**A1**	Comprehensive, covered under technical fee	Technology by use of subject medical device is authorized in any existing reimbursement category and can be used for all insured medicine.
	A2	Specific Procedures trigger supplemental payment	The technology by use of subject medical device is authorized for specific use in the existing reimbursement category.
	A3	Existing A1/A2 but new usage	The technology by use of subject medical device is authorized in any of existing reimbursement category but condition of use is new.
Relevant to STM / DIMM Category Devices	**B1**	Existing functional category, technical fee and separate device fee	"Me-too" functional product reimbursement category. Reimbursable at the same price as existing functional group.
	B2	Existing Functional Category but new usage	The technology by use of subject device is authorized as B1 but condition for use is new.
	B3	Periodical Add-On for Improvement	The technology by use of subject device is authorized as B1 but improvement needs additional price as periodical add-on until new functional group created. (Not applicable C1 or C2)
	C1	New Function	"New products" that are based on existing products or therapies. Technical fee exists for procedure, but a new functional category is needed to account for incremental improvement in technology.
	C2	New Function & New Technology	"New products/therapy" New technical fee and device reimbursement category must be created. Typical C2 categories are breakthrough products involving novel procedures.
	R	Remanufacturing	Items that require a new functional classification as remanufactured products
	F	**Not applicable**	**Not suitable for insured medicine.**

*Sometimes referenced as Designated Insured Medical Materials (DIMM)

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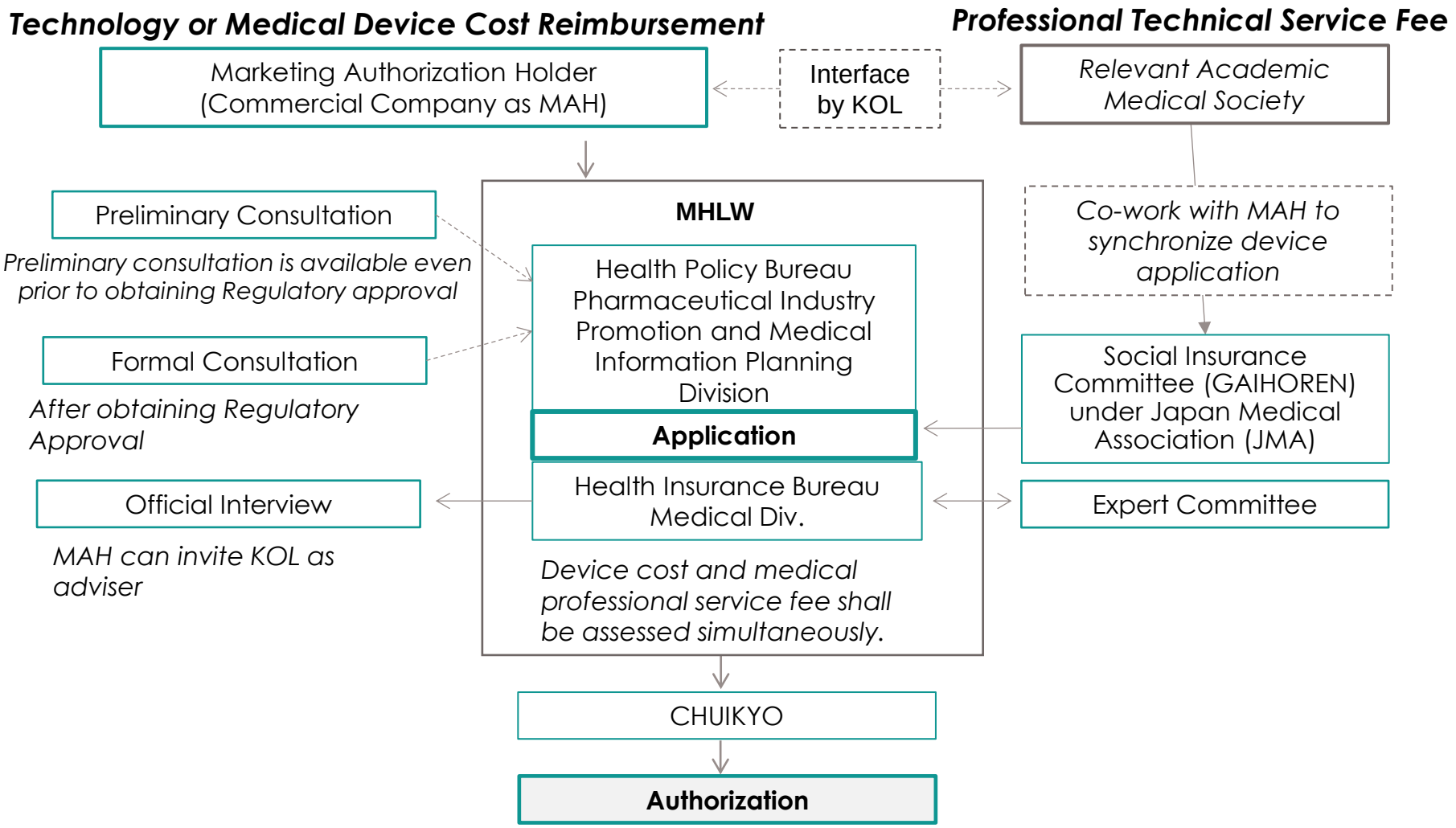
Generally, reimbursement and the professional service fee are determined separately; however, recently, setting the professional fee to include the medical device cost has been the trend.



Reimbursement for the technical fee begins with a physician skill rating by the Gaihoren physician society.

- The Gaihoren is the Surgical Societies of Social Insurance Committees Union and consists of 100 Surgery Societies.
- Every other year, before the MHLW April pricing revisions, Gaihoren proposes revisions for reimbursement to MHLW by using Gaihoren Calculations.
- The Gaihoren proposals include recommendations on technical fees.
- While the Gaihoren proposes a technical fee, the MHLW will often set payment rates at a lower level due to budgetary issues.

Key Gaihoren Factors
• Level of skill needed to perform procedure
• Level of technology
• Number of surgeons required
• Number of assistant nurses required
• Number of technicians required
• Hours of operation
• Total labor cost

Years of experience	Level of Skill	Position
1 year	A	Early clinical resident
5 years	B	Finished early resident
10 years	C	Specialist in basic field
15 years	D	Specialist in Subspecialty field or renewal of specialty in basic field
15 years	E	Specialist with special technology

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The Classification process overall can require upwards of 14 months, depending on the complexity of the procedure coding request.

Flow of Determining Classification of New Medical Devices

- Medical devices, the development and modifications must be completed prior to the review by the Specialist Organization for Insurance Medical Materials (Hozaisen), and it must be confirmed that sales can begin without delay after insurance coverage is applied, and the confirmed results will be reported at the Specialist Organization for Insurance Medical Materials (Hozaisen).
- Insurance coverage begins, with timing depending on category:
  - A1 (Comprehensive): Coverage begins 20 days after application submission (based on certification/approval date).
  - A2 (Specific comprehensive) / B1 (Existing functional classification): For applications submitted by the 10th of the month, coverage begins on the 1st of the following month.
  - A3 (Existing technology/changes) / B2 (Existing functional classification/changes): Coverage begins on the 1st of the month after the month in which classification is determined.
  - C1 (New function) / C2 (New function/New technology) / B3 (Limited-time improvement surcharge) / R (Remanufactured): Coverage begins on one of four scheduled dates per year (March, June, September, December).
- **Exception**: For medical devices used to support decisions on pharmaceutical suitability, insurance coverage may be granted from the 1st of the month following the month coverage for the related pharmaceutical is approved, depending on the pharmaceutical's coverage status.

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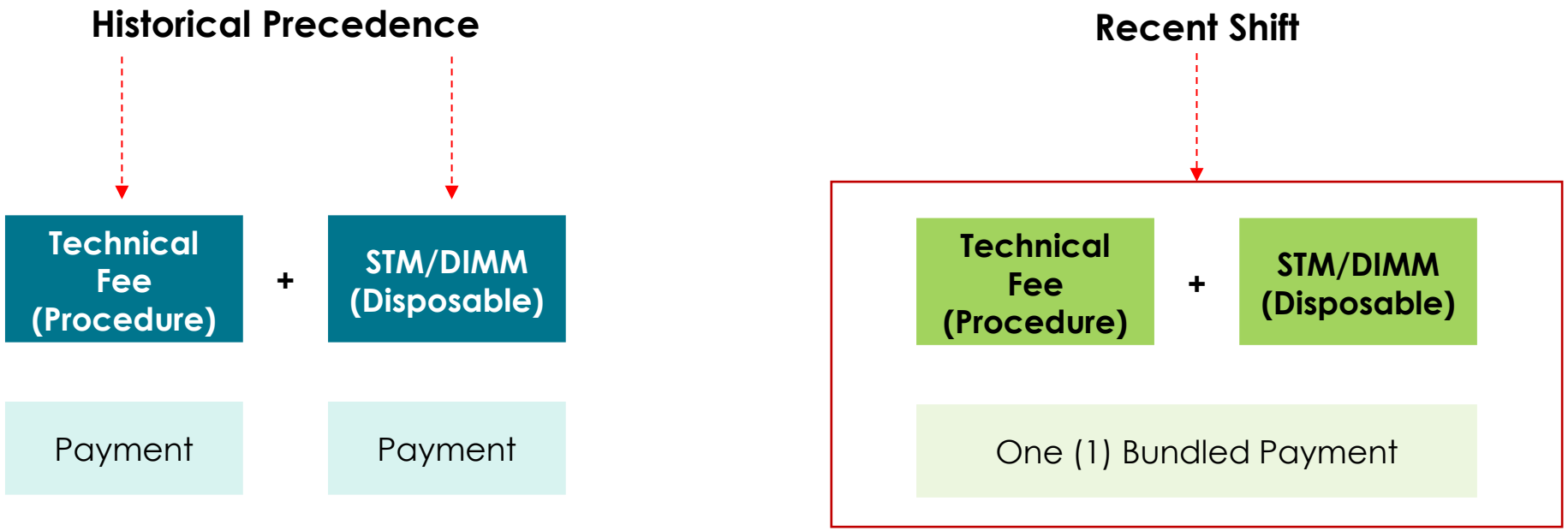
In the last few years, the MHLW has started providing comprehensive Technical Fees for technologies that have C2 approval, wherein the costs of single-use devices (STM/DIMM) are incorporated into a single payment.



The MHLW determines the amount of the new functional category payment by either a comparative or cost calculation methodology.

- There are two possible methodologies that can be applied, depending on the request of the applicant company and the judgment of the MHLW.
- For either method, Marketing Authorization Holder (MAH) must show a rationale to support the analysis.

Comparative Methodology
• Point system for payment of a premium over an existing functional category.
• Used when there is a comparable, existing technology already listed in the DIMM functional category system.
• C1/C2 premiums rarely exceed +15% overall; 4% to 10% is more common.
• Duration: 5 months ~one year
*Calculation Methodology:**
Epochal Function Premium (50% to 100%)
Effectiveness Premium (5% to 30%)
Improvement addition (1% to 20%)
+ Orphan Device Premium (I) (10%)
+ Orphan Device Premium (II) (1-5%)
+ Pioneer addition (10%)
+ Specific use addition (10%)
+ Economic efficiency addition (0.5 × expected cost reduction / Expected average number of uses of the product)
= Price of a material of a new function class

Cost Calculation Methodology
• Cost accounting methodology when there is no similar product in an existing functional category.
• Weakness in the uncertainty of validation of costs.
• Can apply to products where price is otherwise less than 50% of the FAP limit.
• Duration: 5 months ~ one year
Calculation Methodology:
Cost of Production or Importation (Transfer Price)
+Promotion expense
+ General administrative expenses
+ Distribution expenses
+ Operative profit
+ Consumption tax (10%)
= Price of material of a new functional category

*An additional premium, the Improvement Premium, may be applied if the Epochal Function and Effectiveness Premiums do not apply. This ranges from 1 to 20%. Finally, a "Device Lag" Premium of up to 50% may apply if the product is being introduced early into Japan.

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Example: Current myocardial ablation procedures all receive the same technical fee coding and payment.

K595 Percutaneous Catheter Myocardial Ablation

1. Procedures involving atrial septal puncture or epicardial approach: 40,760 points

2. Other procedures: 34,370 points

Note 1: If the test is performed using three-dimensional color mapping, 17,000 points will be added to the specified score as a three-dimensional color mapping addition.

Note 2: If the test is performed using magnetic navigation, 5,000 points will be added to the specified score as a magnetic navigation addition.

Note 3: The cost of diagnostic imaging and examinations associated with surgery will not be charged.

Notice of Implementation Considerations

(1) The three-dimensional color mapping defined in "Note 1" refers to the process of detecting weak electrical signals generated from body surface electrodes using catheter electrodes for external pacemakers (excluding those with magnetic sensors), creating a three-dimensional image of the cardiac cavity, and combining this with the electrocardiogram detected by these catheter electrodes to create a three-dimensional image.

(2) When calculating the three-dimensional color mapping surcharge stipulated in "Note 1," the following cannot be calculated: among the catheter electrodes for external pacemakers of specified medical materials 114, the "intra-atrial/intraventricular full-area type" with added cardiac electrophysiological testing function, and among the percutaneous catheter myocardial ablation catheters of specified medical materials 123, the "external pacing function" and "external pacing function/special type" for thermal ablation.

(3) The magnetic navigation method specified in Note 2 can be billed when performed using a cardiac mapping system workstation.

(4) When percutaneous catheter myocardial cryoablation is performed, the specified points for this category will be billed. In such cases, the procedure must comply with the guidelines for medical treatment established by the relevant academic association.

https://www.mhlw.go.jp/content/12404000/001251499.pdf

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Example: STM categories have a price range from $746 to $3,367.

STM Payments for Thermal Cardiac Ablation Catheters

Percutaneous Catheter Myocardial Ablation Catheter Subcategories	Japan STM Payment (Yen) As of October 2025	Exchange Rate: (1 USD = 150 yen)	Japan STM Payment (USD) (1 USD = 150 yen)
① Standard type	¥112,000	150	$746.67
② Irrigation type	¥140,000	150	$933.33
③ Balloon type	¥505,000	150	$3,366.67
④ With external pacing function	¥293,000	150	$1,953.33
⑤ With external pacing function, special type	¥395,000	150	$2,633.33
⑥ With external pacing function, tissue surface temperature measurement type	¥310,000	150	$2,066.67

Example: The timeline for a C1 application process can take between 4-5 months time for review if an application is complete. In practice, 6-9 months is not unusual.

- Applications may be submitted once a quarter.
- The review time target is 80 business days for C1 and 100 business days for C2 products.
- MHLW will approve C2 reimbursement officially on the first day of January, April, July and October.

Application Category	Date of Submission		Timeline for Reimbursement
	C1	C2	
	4 months for review	5 months for review	
C1/C2	October 31st	September 30th	April 1st
	January 31st	December 31st	July 1st
	April 30th	March 31st	October 1st
	July 31st	June 30th	January 1st

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Foreign Average Pricing (FAP) is used to cap new STM / DIMM functional categories; **pricing for products in relevant reference markets will have a direct impact on Japanese reimbursement.**

FAP Calculation for New STM / DIMM Products

$$\frac{\textbf{(US + UK + Germany + France + Australia)}}{\text{5 (Number of countries pricing was submitted for)}}$$

FAP Ceiling = FAP x 1.3

- Japan looks to the established price for new technologies that are receiving new STM / DIMM functional categories (C1 or C2) in the following reference markets: the United States, the United Kingdom, Germany, France, and Australia.
  - FAP is only used for technologies that are being priced through the cost calculation methodology.
- The maximum Japanese price will be 1.3x the simple average price of these markets for new products.
  - Historically, the the FAP ceiling for existing products was 1.5x the FAP limit.
- Although there is no specific stipulation on providing the list price versus the acquisition price, the MHLW has asked for acquisition prices.
  - Despite this, many industry submissions have still relied on list prices and been successful.
- The FAP is also used to make ongoing cuts to existing STM / DIMM products. The maximum cut for existing products is 25%.

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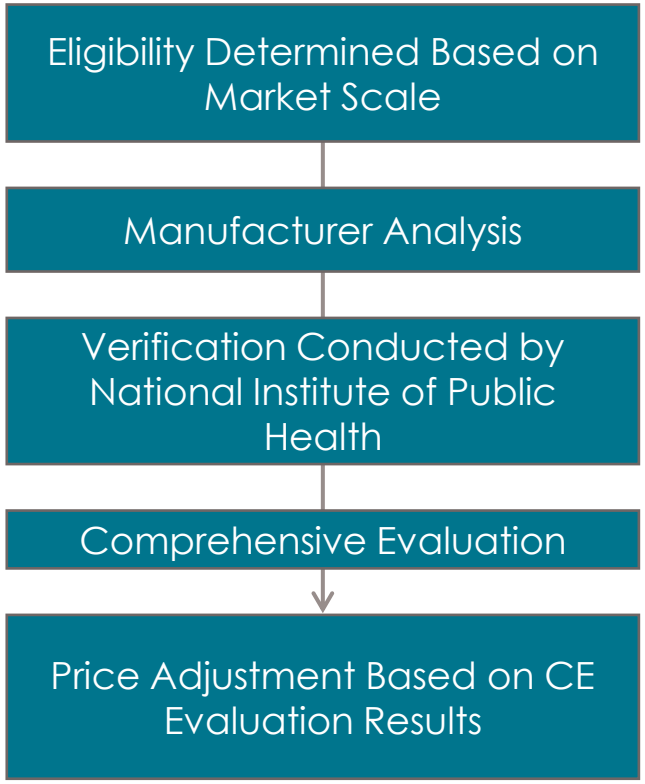
Cost-effectiveness evaluation in Japan.

Chuikyo Cost-effectiveness Classification System

Classification	Code	Selection Criteria
Newly listed products	H1	Estimated peak annual sales of > ¥10 billion
	H2	Estimated peak annual sales of ¥5-¥10 billion
	H3	Products with notably high price or requiring re-evaluation based on new evidence
Already listed products	H4	• Annual sales of > ¥100 billion and H3 • Products deemed necessary based on Chuikyo review of high unit prices
Similar products	H5	Products whose prices are calculated comparatively against those categorized in the H1 to H4 classifications

Cost-effectiveness Evaluation Overview



As of May 2024, only two (2) medical devices had been subjected to a cost-effectiveness-based health technology assessment (HTA).

- After an initial pilot launch in 2016, the Central Social Insurance Medical Council (Chuikyo) fully implemented a QALY-based cost-effectiveness system in 2019.
  - Various ICER thresholds are used in Japan based on the product characteristics and rage from ¥5 million / QALY and ¥10 million / QALY.
- Designated medical devices are selected based on a 5-tier classification system, primarily based on the predicted annual peak sales and degree of innovation.
  - Medtronic's Micra Transcatheter Pacing System and JnJ's Expedium Verse Fenestrated Screw System are the only two (2) medical technologies subject to an HTA.
- Products for rare diseases, hemophilia, and human immunodeficiency virus (HIV) are excluded.

MHLW evidence review process will primarily focus on incremental clinical benefit; cost-effectiveness requirements only apply to certain devices.

- MHLW will focus on comparative studies with evidence of superiority in its evaluation.
- The comparative methodology depends on evidence of incremental improvement over existing devices.
- Local Japan studies, while preferred, are technically not mandated for PMDA approval and MHLW reimbursement.
- We have found such studies more common where MHLW believes there are population differences as compared with Western patients.
- It is uncommon for PMDA approval and MHLW reimbursement to occur before US and European regulatory approval.
- However, MHLW maintains a special SAKEGAKE (device lag) premium of 50% may be applied for devices being introduced early into Japan.

Cost Effectiveness Evaluation (HTA) Requirements

- Generally, HTA evaluations are only conducted on medical devices with a peak market forecast of 5 billion yen (approx. 33.3 million US$) and to which a utility premium has been applied.
- If the results of the cost-effectiveness evaluation analysis do not meet certain standards, a price adjustment will apply.
- The price adjustment applies only to the premium portion, and does not apply to the base price portion.
- Since the introduction of the system, medical devices that have been subject to HTA evaluation were "H2" category (market size of 5 billion yen or more).

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