

Reimbursement Price Revision of Medical Devices in Japan

An explanatory paper

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Executive Summary

Objective

To describe how medical device prices are revised in Japan.

Importance to APACMed members

- Japan is the largest medical device market in Asia and second largest in the world, after the US
- Reimbursement is key for market access in Japan – there is virtually no private system
- Focus on pricing is increasing given the ageing population and pressure on Government budgets, including health.

Current state

- Reimbursement prices are revised every two years based on market prices and/or foreign reference pricing.

Potential future changes

- Results of HTA, or cost-effectiveness analysis, will be used to inform price revisions
- The Ministry of Health, Labour and Welfare (MHLW) is considering implementing annual revisions, as they do for pharmaceuticals.

Introduction

This overview describes how the reimbursement prices of medical devices are revised in Japan. The price determination for new devices will be addressed in a separate document.

Medical device reimbursement in Japan

The Ministry of Health, Labour and Welfare (MHLW) oversees the National Health Insurance (NHI) system of Japan. Under the MHLW, the Central Social Insurance Medical Council (often called Chuikyo) provides advice regarding reimbursement price and policy of technical fee, drugs and devices to MHLW. MHLW reviews all reimbursement policies every two years, including fees and discount policies.

Medical devices are covered under supplemental physician service fees or medical procedures (technical fees), which include the costs for diagnostics, treatment, low price and re-usable devices, surgical material, procedures and staff costs. If they are considered special treatment materials (STM), however they will be reimbursed separately from the technical fees at the prices specified by their functional category. Devices that have a similar structure, intended usage, clinical efficacy and effectiveness are allocated to the same functional category and brand names are not listed on the STM list. Currently there are 900 functional categories (excluding devices for dentists and pharmacies)¹.

There isn't a clear definition of what makes a device eligible for the STM list but they are typically single use devices. The usage quantity and the price of the device relative to the associated technical fee are also factors taken into consideration in determining eligibility.

Biennial revision

The reimbursement prices for devices on the STM list are currently reviewed every two years as according to the "Standards for insurance reimbursement price for special treatment materials"². There are two price surveys used to determine price reductions – market prices and foreign prices. The biennial revision also includes the price changes due to functional category mergers and splits. For STM products, the reimbursement fee is revised based on market price-based revision, Foreign Average Price repricing, unprofitable repricing and category restructuring.

Market price weight survey

The retail price of a medical device is determined by negotiation between hospitals and distributors. The price can be lower or higher than the STM reimbursement price. The aim of the price survey is to evaluate the margin between the reimbursement price and the average price paid by hospitals, as the price negotiated by hospitals might differ from the reimbursement price. If the margin is deemed too high, the MHLW will lower the reimbursement price.

The price survey usually covers a five-month sales period from May 1st to September 30th in the year prior to the planned implementation of the new prices. All distributors are required to provide price and volume data, along with a sample of hospitals. Manufacturers also need to provide detailed product information to enable appropriate adjustments to the pricing data to be made e.g.

¹ STM list, as at April 1, 2019

² Criteria for calculating insurance reimbursement prices for specified insured medical materials, MHLW, HOHATSU 0329-3, dated March 29, 2019

what accessories are included or not included in the price of a device, if a device set includes multiple STM items or if a device is in more than one functional category due to multiple indications for use.

Foreign price survey

Every year, MHLW selects around 130 – 150 functional categories to survey foreign list prices. Manufacturers are required to provide the list prices of their devices in the US, UK, Germany and France. For functional categories with a price decided after April 2012, the price in Australia must also be provided. MHLW collates the data from the manufacturers to calculate a country price for each functional category from which the foreign average price (FAP) is calculated. However, high-priced country outliers are excluded or adjusted if:

- The highest country price is 2.5 times the lowest country price (it is excluded)
- The highest country price exceeds 1.8 times the average of the others (it is replaced with 1.8* the average price).

Price revision

The standard method calculates the new reimbursement price for a functional category, using the following formula:

New reimbursement price = weighted market price average + consumption tax + reasonable premium (currently 4% of the existing reimbursement price).

The price is then compared to the FAP and if it is greater than the FAP*1.3, then the following “recalculation formula” is applied instead:

New reimbursement price = old reimbursement price * [(FAP*1.3)/weighted market price average].

Note: the new reimbursement price cannot be less than 75% of the old reimbursement price.

There is possibility for manufacturers to apply for increased reimbursement price for unprofitable products, although the process is complicated and the success rate is very low.

Exceptions

There are special exemption rules for devices that were recently allocated to new functional categories. For example, if a new device is allocated to a new category with a premium (of at least 10%) for innovation or usefulness, then the price surveys for this device will be calculated separately from other ‘me-too’ type products that are subsequently added to the category. This special exception expires after two revisions. Other exceptions include orphan or high clinical need devices.

Implementation

An unofficial draft of the new reimbursement prices is normally released around January and manufacturers can appeal if they think a calculation error has been made. Prices are finalised by early March and effective from April 1st to coincide with the new financial year.

Recent update: Cost-effectiveness assessment revision

In April 2016, Chuikyo selected 10 health technologies (drug, medical device and diagnostics) to undergo the HTA pilot with Cost-Effectiveness Assessment (CEA). The selection criteria were therapeutic goods having a high price or a high premium. Subsequently the MHLW announced a full-scale CEA scheme implementation from April 1st, 2019. At present, the results of CEAs will be used for post-listing reimbursement price adjustments only, not for reimbursement decisions. The Ministry, however, will continue to explore the application of CEAs.

MHLW proposed a system with a slope-like price-adjustment within the premium portion of the reimbursement price, based on the Incremental Cost-Effectiveness Ratio (ICER) results.³

Selection criteria for CEA

Health technologies eligible for CEA would be “highly innovative and financially impactful drugs and medical devices” that receive innovative or effectiveness premiums at the time of listing. They are classified into five categories, depending predominantly on whether they were listed before or after April 1st 2019 and when the peak sales forecast reaches ¥5 – 10 billion or more.

The MHLW, being mindful of patient access and innovation needs, has excluded health technologies for rare diseases (small number of patients, state-designated intractable diseases, hemophilia, and HIV), pediatric use, and oncology from CEA. At the discretion of Chuikyo, financially impactful products might be included in the scope even if they fall under these exemptions.

CEA Process

Manufacturers would have nine months to complete CEA analysis, from pre-analysis discussions (three to six months) to actual analyses (three to six months). Following the CEA results, three months are given for public analyses (six months if re-analyses are to be conducted), and another three months for appraisals and pricing.

Appointed public analysis groups, comprised of several universities and academic institutions, need to be consulted by manufacturers at the start of CEA process, to define the framework of CEA analyses, such as target populations, comparator technologies, and data to be analysed.

Price adjustment rules

The MHLW details the new price adjustment rates, separately for the premium portion and operating profit portion (cf. Figure 1).⁴

³ <https://www.mhlw.go.jp/content/12404000/000472473.pdf>

⁴ <https://pj.jiho.jp/article/239256>

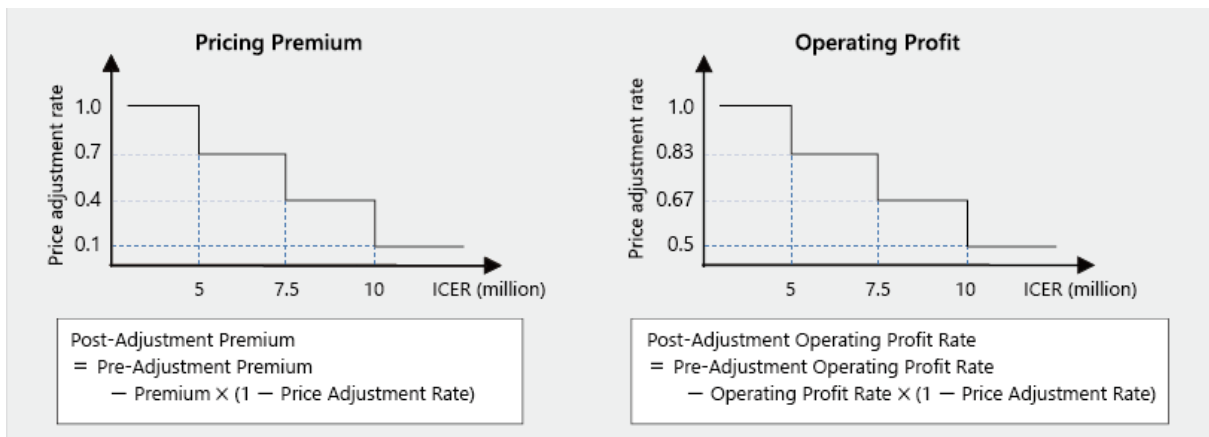


Figure 1. CEA Price adjustment rates

The maximum CEA-based reimbursement price reduction rate is set at 10 – 15%, depending on the rate of premiums granted at launch.

Price rises for below two million Yen/QALY or dominant technologies

Reimbursement prices could be raised based on the results of CEAs:

- For “dominant” health technologies (demonstrating cost savings while offering benefits equivalent to, or higher than, comparator technologies products): they could get 50% rise on their premium portions, with the upper ceiling set at 10% of the overall reimbursement price, if meeting all criteria
- For technologies with ICERs below 2 million Yen/QALY: a 25% rise could be given on their premium portions, with the cap set at 5% of the total reimbursement price, if the evidence meets the strict requirements.

Conclusion

- MHLW have progressively reduced prices and tightened the FAP rules
- There are adhoc price cuts in addition to the regular bi-annual revisions
- System could move to yearly reviews, as seen with pharmaceuticals – this raises concerns around the administrative burden placed on hospitals, distributors and manufacturers vs the discounts that can actually be achieved
- The cumulative effect of Japan's newer price reductions, HTA and the reduction in device price premiums is expected to significantly contribute to greater overall pricing pressure.