Japan’s Health Insurance System and Reimbursement for AI Medical Devices

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April 29, 2026, CHOICE Graduate Seminar

Key questions for this talk

- Is Japan's current cost-sharing model reaching its limit?
- Can the current pricing scheme capture the value of innovation?
- Can the current regulatory and pricing evolution balance technological innovation with the long-term sustainability of the healthcare system?

Agenda

1. Overview of Japan’s Public Health Insurance System

2. Medical Regulatory Approval and Reimbursement

3. Approval and Reimbursement for AI Medical Devices

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Universal health coverage and demographic challenges

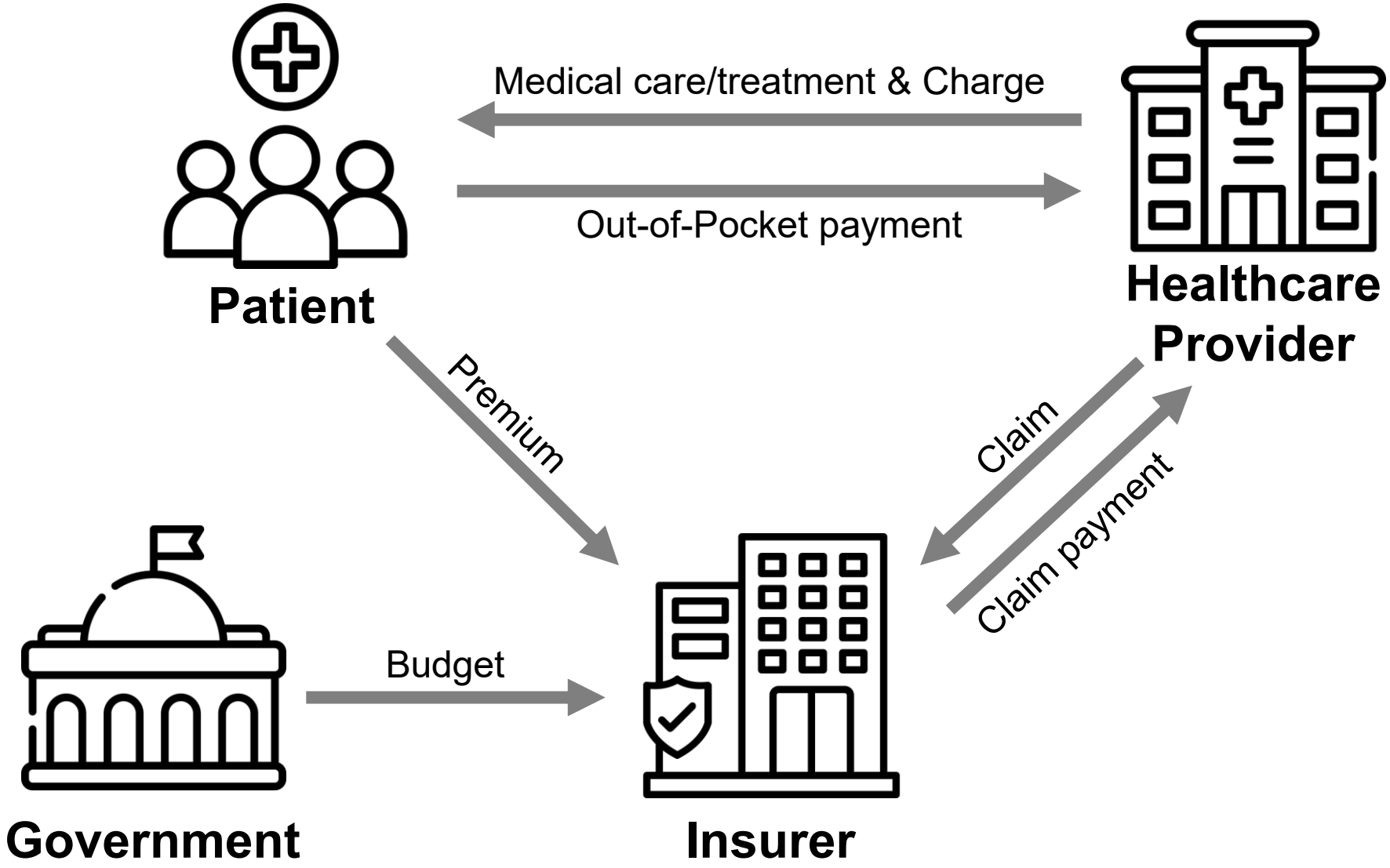
While supportive public health insurance system is available in Japan, its sustainability and robustness are under increasing strain

- Nearly 100% of the population is covered by public health insurance

- Demographic changes posing big concerns about sustainability
  - Aging (approx. 30% over 65 yo)[1]
  - Declining birth rate (1.15–1.2 child births per woman lifetime)[2]
  - Regional disparities in healthcare providers and age distribution

1: Annual Report on the Ageing Society FY2025. Cabinet Office Japan. 2025. https://www8.cao.go.jp/kourei/english/annualreport/2025/pdf/2025.pdf
2: Annual Health, Labour and Welfare Report 2025. Ministry of Health, Labour and Welfare https://www.mhlw.go.jp/wp/hakusyo/kousei/25-2/index_en.html

Japan's healthcare system



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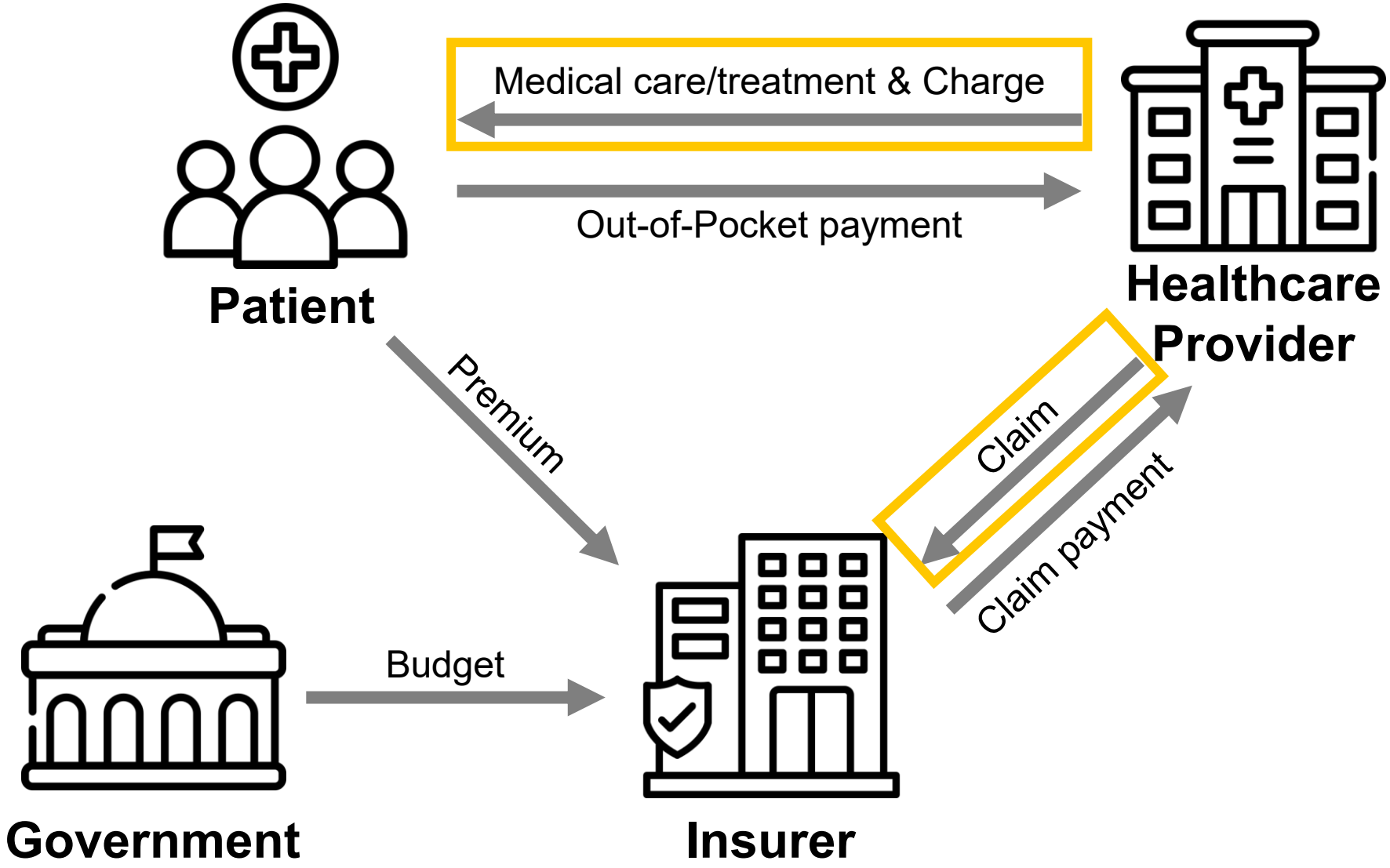
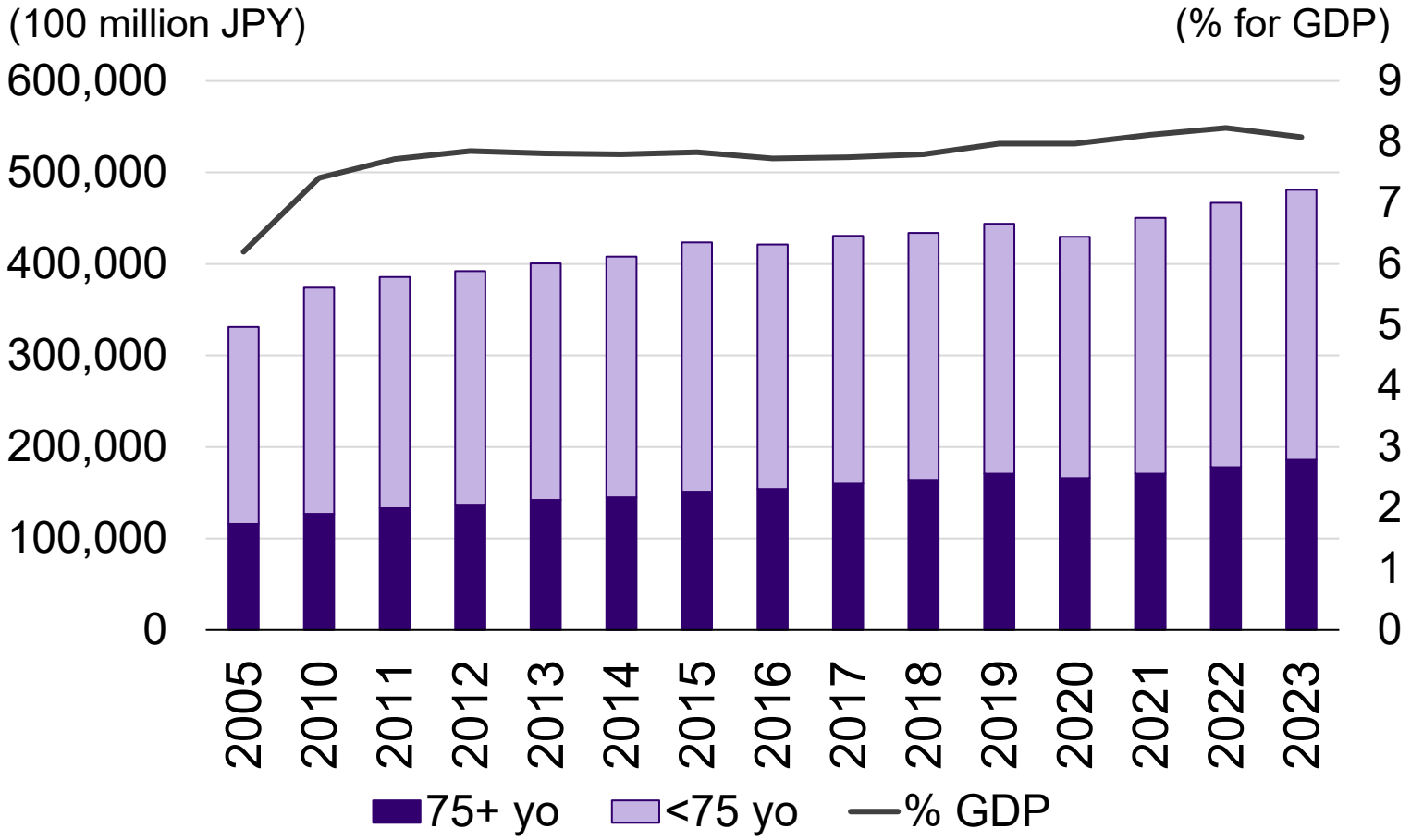


Rising health expenditure due to aging

Health expenditure has been rising by 2-3% every year. The growth rate for ≧75 yo is larger than the overall growth rate



In 2023

- Overall: 48 trillion JPY ($302 billion)
- ≧75 yo: 18.6 trillion JPY ($117 billion; 40%)
- 8.1% of GDP

Annual Health, Labour and Welfare Report 2025. Ministry of Health, Labour and Welfare https://www.mhlw.go.jp/wp/hakusyo/kousei/25-2/index_en.html

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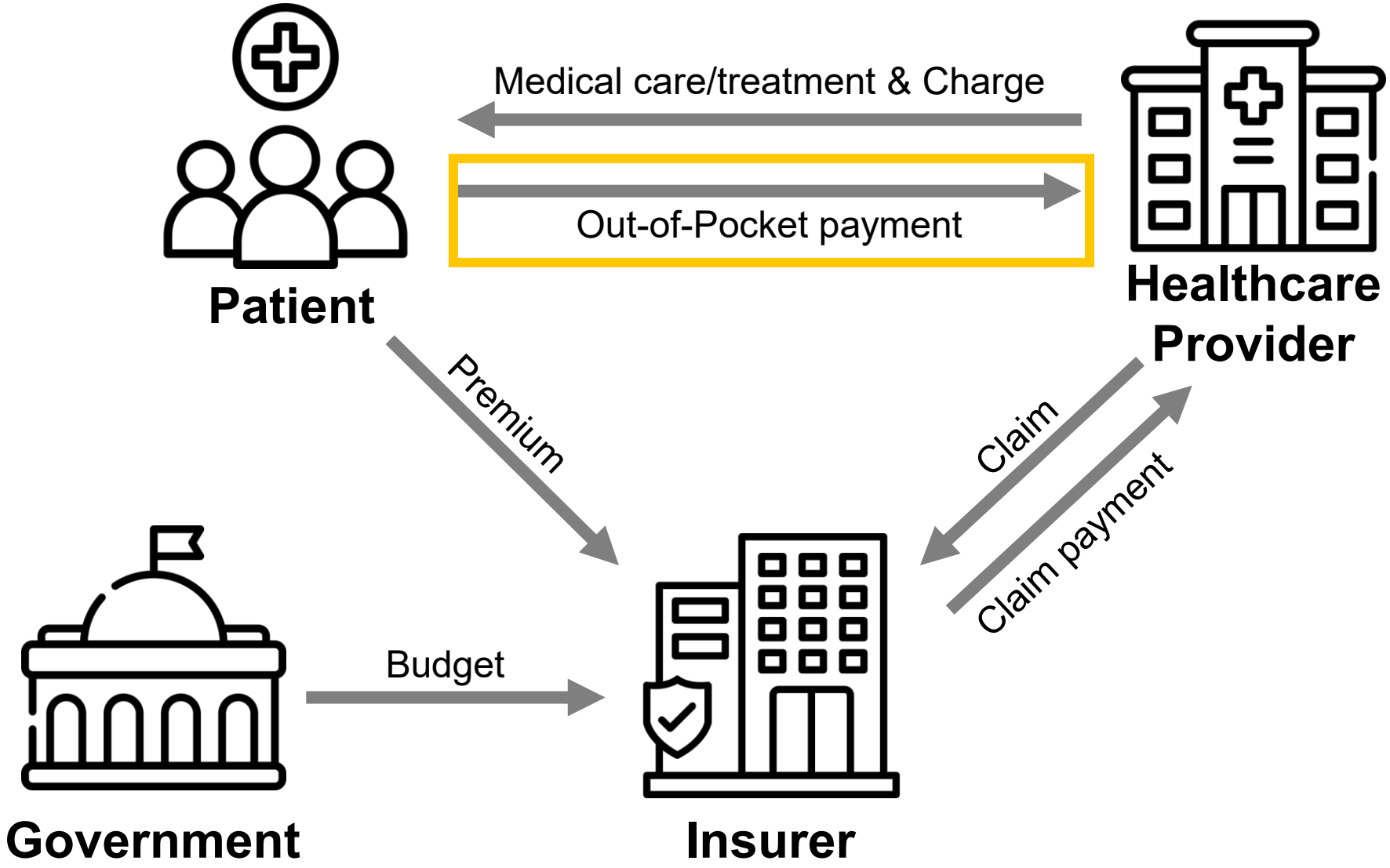
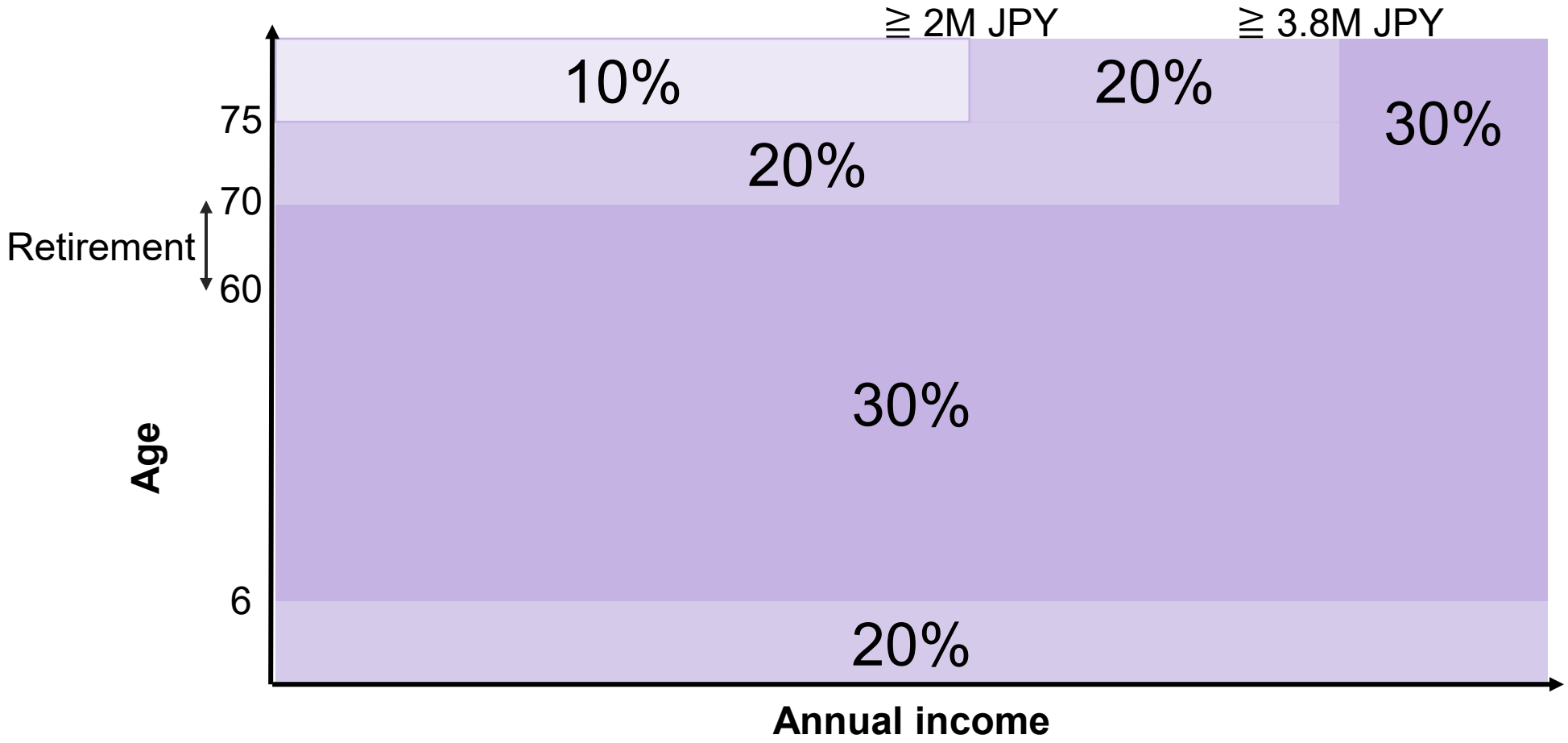


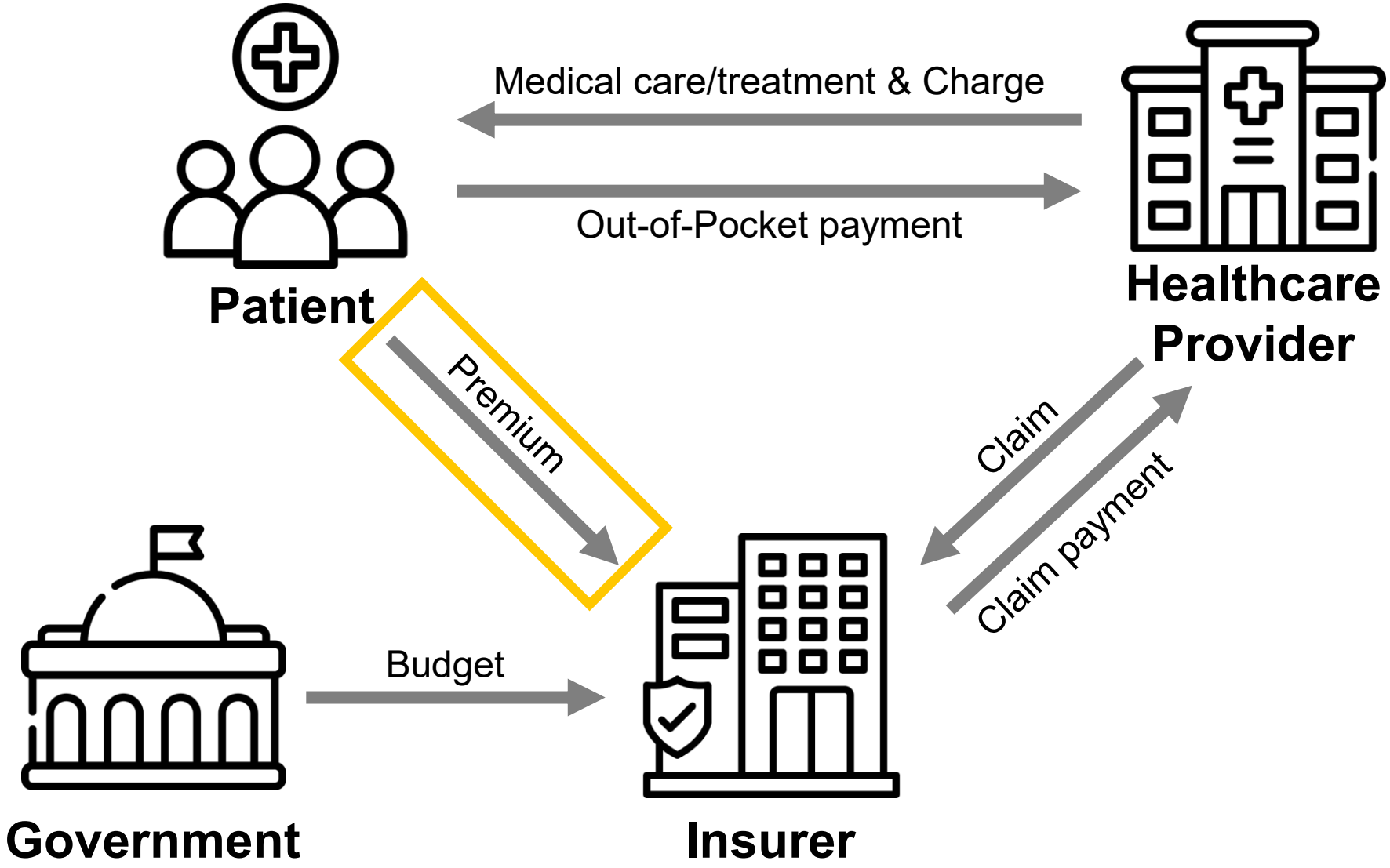
Different coinsurance by age and income level

To support vulnerable populations with lower income and higher healthcare needs, coinsurance differ by age and income



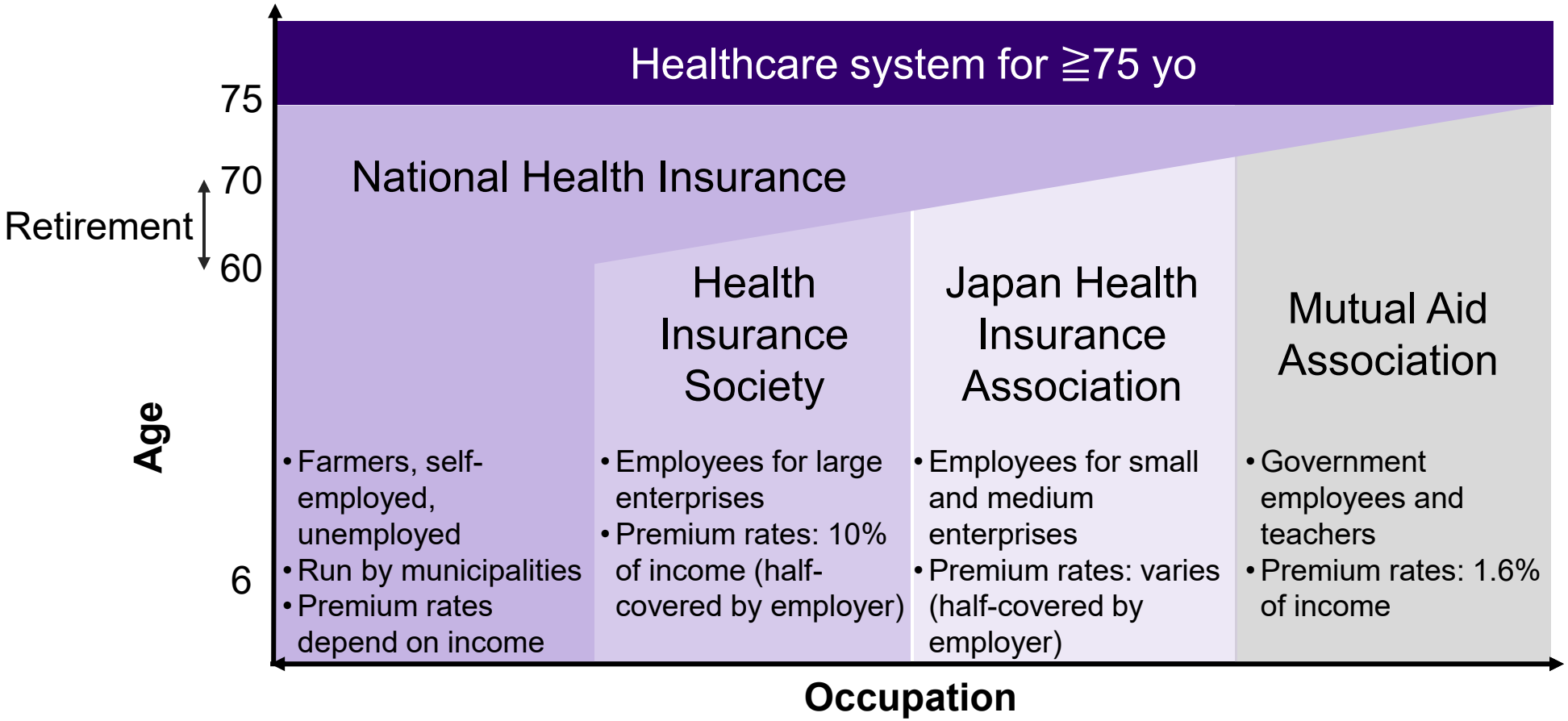
Annual Health, Labour and Welfare Report 2025. Ministry of Health, Labour and Welfare https://www.mhlw.go.jp/wp/hakusyo/kousei/25-2/index_en.html

Japan's healthcare system



Different insurance provider by age and occupation

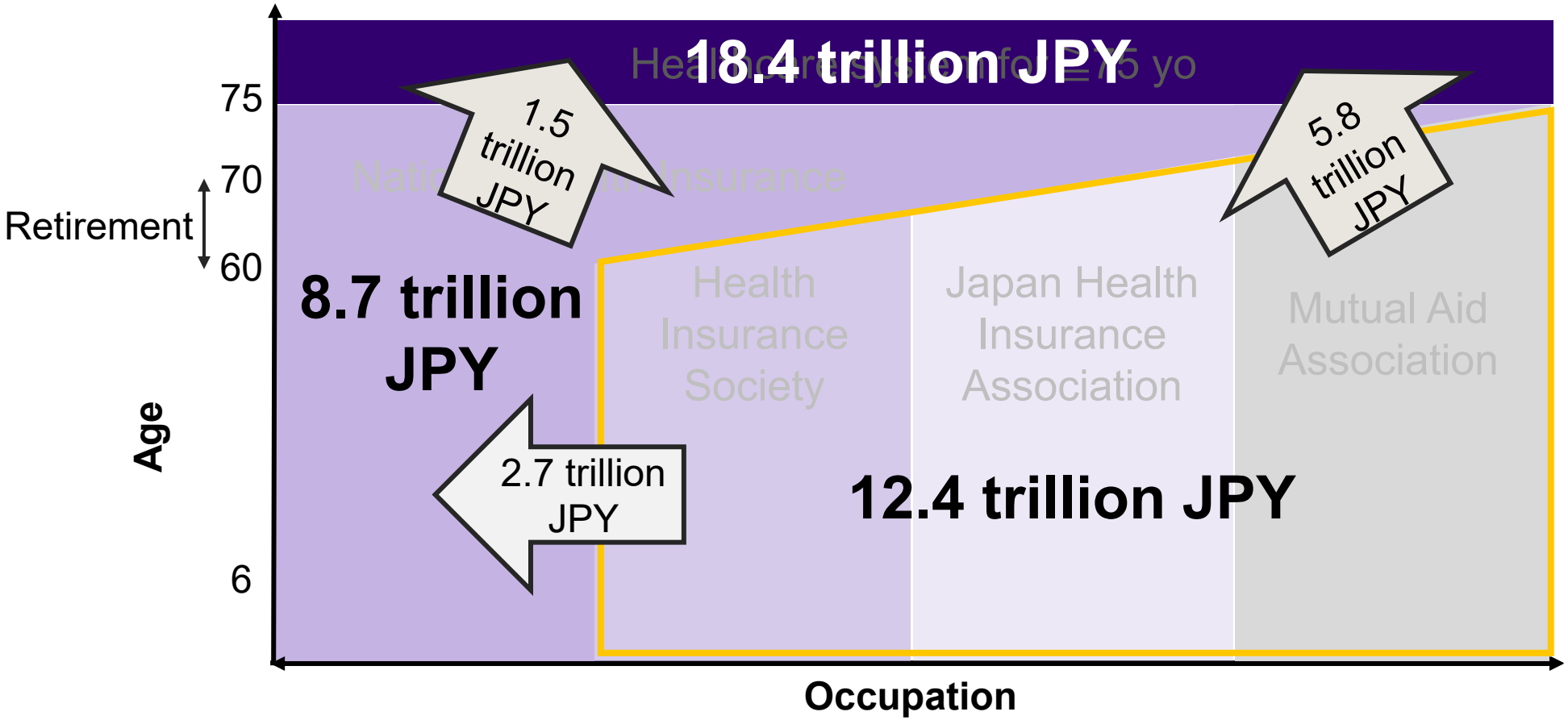
To accommodate different work styles and health risks, 3,000+ health insurers serve the population under 5 sub-systems



Annual Health, Labour and Welfare Report 2025. Ministry of Health, Labour and Welfare https://www.mhlw.go.jp/wp/hakusyo/kousei/25-2/index_en.html

Reallocation of budgets

To fill the gap between budget and expenditure for vulnerable population, budgets are reallocated from employment-based insurance to the others



Ministry of Health, Labour and Welfare https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/iryouhoken01/index.html

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Nationwide standardized points

Medical services covered by public health insurance are charged by points, determined by fee schedules

Medical Bill Statement (example)

Outpatient 保険

ID		Name ○○ ○○ 様	Date	YYYY/MM/DD
Fee				

部	Medical Services	Points	Time
Basic fees	＊Outpatient consultation fee	73	1
Home care	＊Self-injection guidance and management fee	750	1
	＊Additional charge for self-monitoring of blood glucose device	1490	1
Prescription	＊Prescription fee	68	1
Lab tests	＊Biochemical test (I) interpretation fee	144	1
	＊Hematological test interpretation fee	125	1
	＊B－V	30	1
	＊Laboratory test management surcharge	40	1
	＊Blood microorganisms	40	1
	＊Biochemical test (I)	112	1

Points

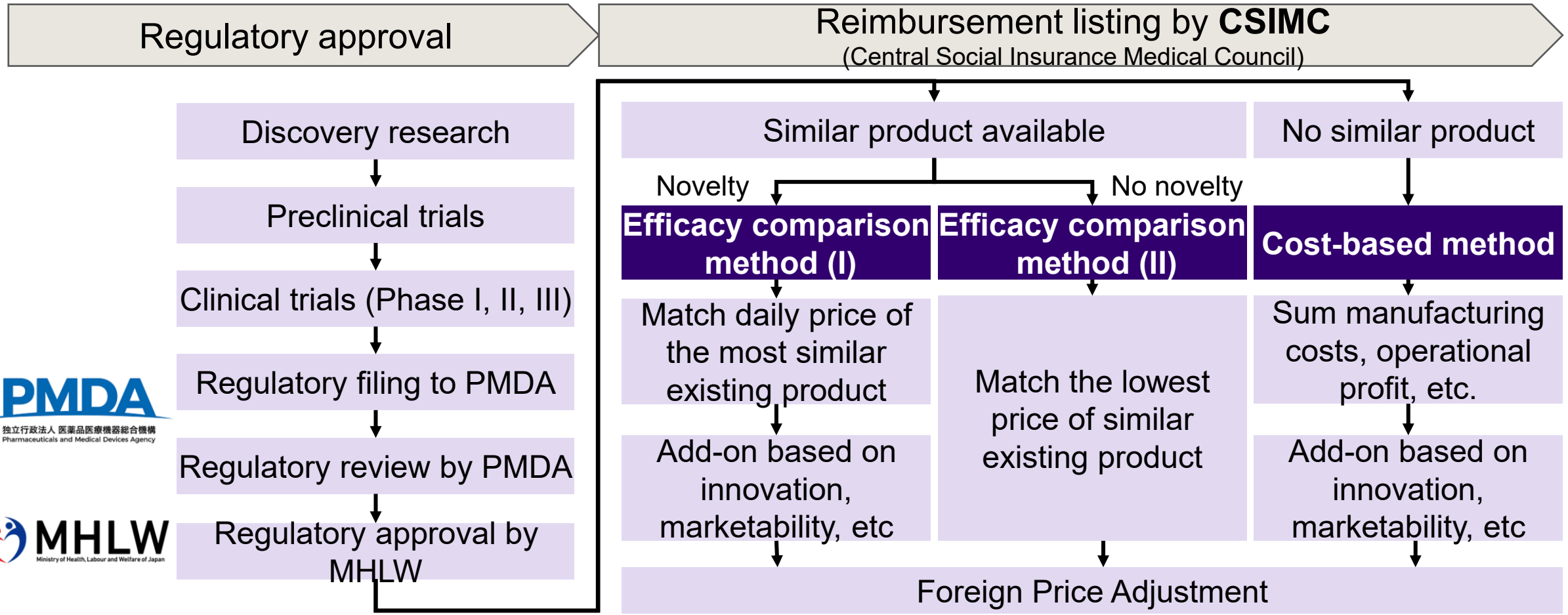
- Assigned to all medical services, drugs, and technologies covered by insurance
- Standardized nationwide

Patients pay…
Points x time x 10 x coinsurance (%) JPY

Ministry of Health, Labour and Welfare https://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000203025.pdf

Regulatory approval and listing for reimbursement

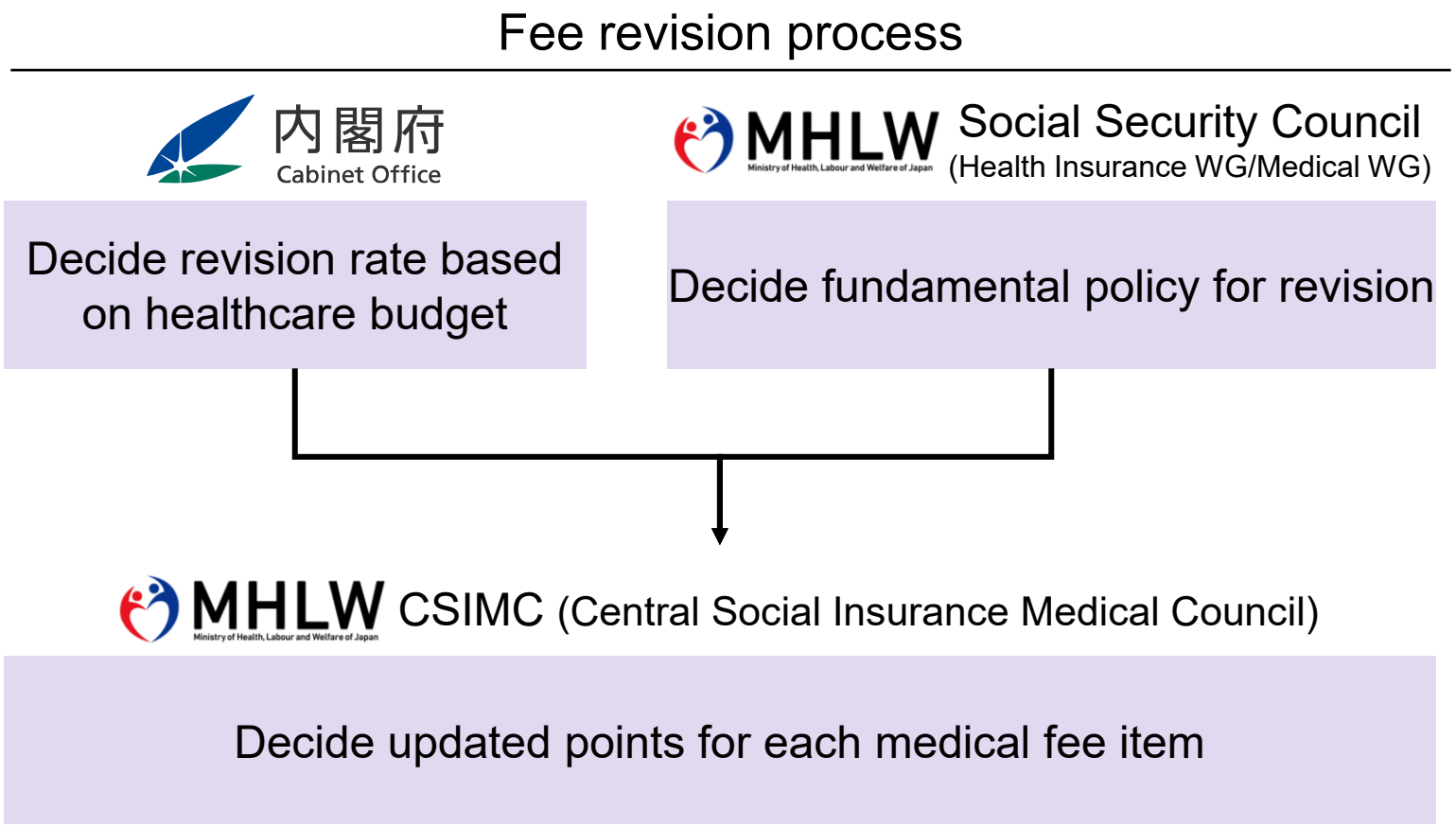
Medical services, pharmaceuticals, and medical technologies must be approved and listed in fee schedule to be covered by health insurance



Pharmaceuticals and Medical Devices Agency (PMDA) https://www.pmda.go.jp/files/000263354.pdf
Central Social Insurance Medical Council https://www.mhlw.go.jp/content/10808000/001508748.pdf

Fee schedule revision

Medical fee schedule is revised every other year considering the overall national budget and basic policy.



FY 2026 revision

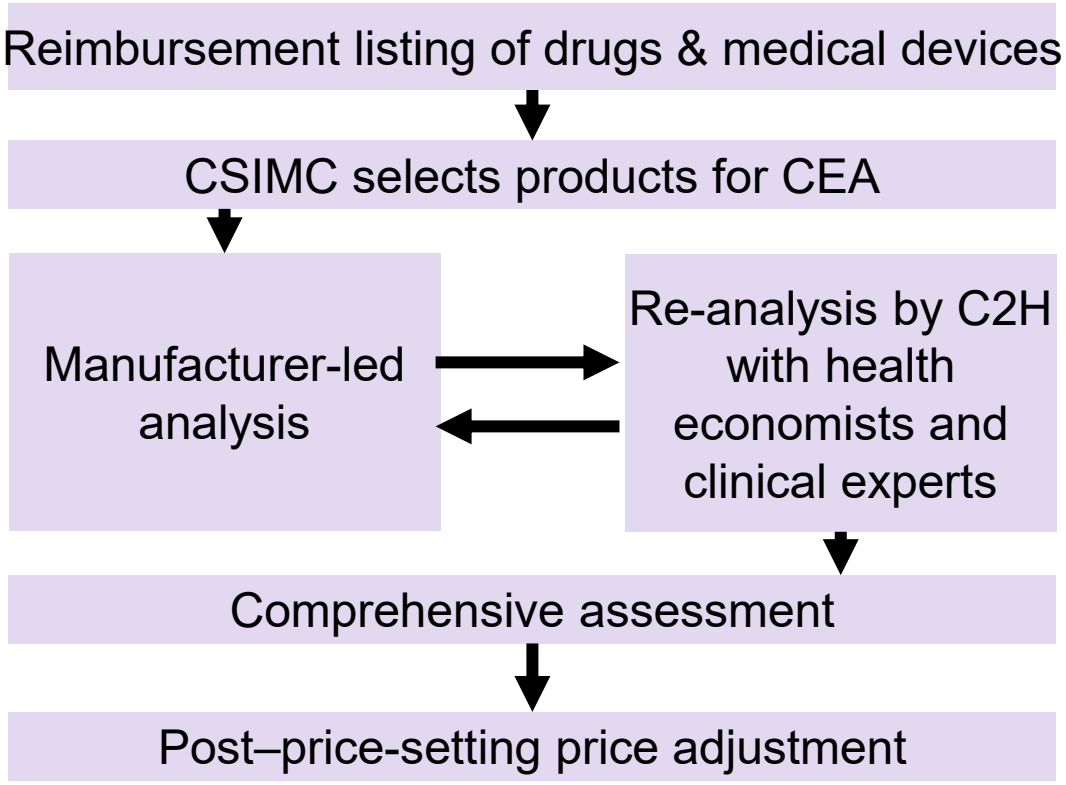
- Service fee: +3.3% driven by rising wage pressures
- Pharmaceutical: -0.86%
- Medical device: -0.01%

Ministry of Health, Labour and Welfare https://www.mhlw.go.jp/content/12401000/001137908.pdf

Role of Health Technology Assessment

CEA was introduced in 2019 only for fee schedule revision of drugs and devices with large market sizes or high unit prices

Process



Key Points

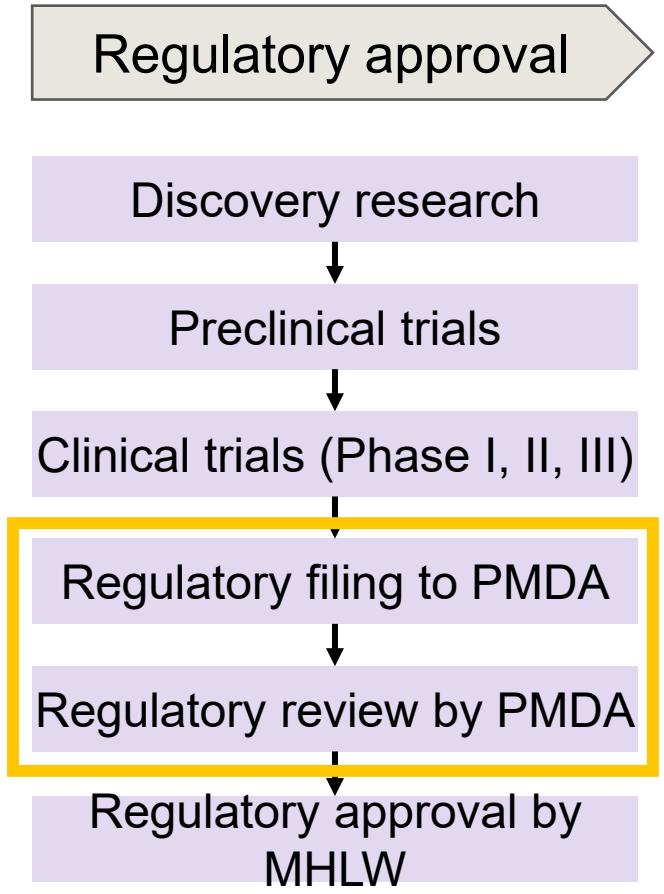
- Introduced in FY2019 due to rising healthcare costs
- Applied only to products with large market size or very high unit prices
- Manufacturer analyses are reviewed and re-analyzed by C2H (Center for Outcomes Research and Economic Evaluation for Health) with domain experts
- After comprehensive assessment, products with poor cost-effectiveness (≥ 5M JPY/QALY≒ $32K) may face price cuts; products contributing to cost savings may receive price increases
- Challenge: Limited evaluation capacity—currently about 10 products per year; workforce development is needed.

Ministry of Health, Labour and Welfare https://www.mhlw.go.jp/content/12400000/001666329.pdf

Regulatory approval specific to medical device

Medical device is categorized into 4 classes depending on the risk in the event of malfunction. The class determines the approval process and speed

Class	Definition	Approval Process
I	Very low risk to the human body even in the event of a malfunction (e.g., X-ray film, scalpel)	Self-declaration (Submission only)
II	Relatively low risk to the human body even in the event of a malfunction (e.g., MRI machine, ultrasound machine)	3rd party certification
III	Relatively high risk to the human body in the event of a malfunction (e.g., ventilator, dialysis machine)	3rd party certification **/PMDA approval**
IV	Life-threatening risk in the event of a malfunction (e.g., pacemaker)	**PMDA approval**



Pharmaceuticals and Medical Devices Agency (PMDA) https://www.pmda.go.jp/files/000274829.pdf

Reimbursement listing specific to medical device

For some, value of technology is included in service fee. For others, it can be charged as “functional category” fee, separated from service fee

Application category	Device	Medical service	Evaluation in fee schedule
A (A1, A2, A3) Existing service fee **include** reimbursement for new device	Needle	Blood collection	Service fee points for blood collection include the value of needle
	Ultrasound machine	Ultrasound examination	Service fee points for ultrasound examination include the value of ultrasound device
B (B1, B2, B3) New device can be covered by existing “functional category” for technology **separated from** service fee	Pacemaker	Pacemaker implantation	Service fee points for implantation **+** technology fee for pacemaker
C (C1, C2) Fee schedule needs to create new “functional category” for new device	New device	-	Service fee does not cover medical technology fee for new device and new “functional category” is needed

MHLW https://www.mhlw.go.jp/content/10800000/001073851.pdf

Matsumoto et al. Current Medical Technology Reimbursement System in Japan *Value in Health Regional Issues*, 2023; 34, 118-12

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Financial difficulties at macro-level and micro-level

Downward pressure of healthcare expenditure and shortage of medical workers and demand new medical technologies

- Pressures to restrict healthcare expenditure from national perspective

- Financial difficulties and labor shortages in healthcare providers
  - Uneven distribution of healthcare professionals by region and specialty
  - Rising costs such as personnel and utility expenses due to inflation
    - Record high of 717 hospital bankruptcies and closures in 2025
    - 80% of university hospitals are in the red

➢Improving productivity through AI medical devices may help address labor shortages and improve hospital finances

➢Whether the devices receive insurance coverage and how points are allocated will be the key to widespread adoption

Difficulty in evaluating AI medical device

AI is intangible and its effectiveness and function can vary, which causes difficulty in categorizing AI medical devices within existing framework

- Regulatory approval
  - Is it a "medical device" or not?
  - If so, which Class (I-IV) does it fall under?
  - Is it possible to do test marketing?

- Reimbursement listing
  - Which application category (A1-C2) applies?
  - Any add-on evaluation beyond typical tangible medical device?

- Fee schedule revision
  - Any add-on re-evaluation for post-marketing improvement?

Regulatory approval for AI medical device

51 AI medical devices had been approved until Sep 2025. Many devices use image recognition while recent approvals granted to diverse applications

Class	Risk to patients	Examples of AI medical device	
Not medical device	None	•Medical record creation via voice recognition •Fitness apps	
I	Very low (e.g., X-ray film)	NA	
II	Relatively low (e.g., MRI machine)	•Behavioral change apps •Smartwatch irregular rhythm notification	Image diagnosis
III	Relatively high (e.g., ventilator)	•Genetic mutation analysis •Treatment planning support •Surgery support •Device control programs	
IV	Life-threatening (e.g., pacemaker)	NA	

Two-stage approval system

- 1st stage approval: Market launch with a limited intended use
- 2nd stage approval: Obtain second-stage approval based on RWD (Real World Data) or clinical trial results

➢This system can significantly shorten the regulatory approval period (from over 4 years to approx. 1 year~).

Pharmaceuticals and Medical Devices Agency (PMDA) https://www.pmda.go.jp/files/000274829.pdf

Reimbursement listing and revision for AI medical device

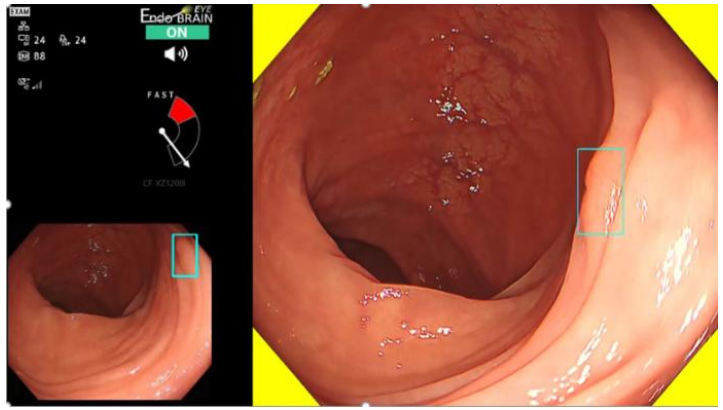
Appropriate price for AI medical device remains unclear and is evaluated on a case-by-case basis

- Reimbursement listing
  - Many AI medical devices are filed under C1/C2 categories (new “functional categories”)
  - While "Cost-Based Method" is the principle for devices with no comparators, the definition of "costs" remains ambiguous
    - Industries are advocating for the inclusion of server management fees and cybersecurity costs
    - Evaluations remain on a case-by-case basis
  - Most devices currently secure reimbursement via "Comparison method + Add-on premiums“
  - Now possible to claim specialized fees such as “Program Management Fees” or “Program Guidance Fees” as add-ons
- "Challenge Application" system
  - Mechanism to re-evaluate points after listing, based on real-world clinical performance
  - Requires high-level clinical evidence, such as peer-reviewed publications
  - Due to this rigor, some companies end up withdrawing their applications

MHLW https://www.mhlw.go.jp/content/12404000/001168428.pdf https://www.mhlw.go.jp/content/10808000/001568750.pdf

Example I. EndoBRAIN-EYE®

While AI increases detection, it raises concerns about unnecessary surgeries and higher healthcare spending



- AI analyzes endoscopic images in real-time during a colonoscopy
- When the system detects a potential lesion (polyp), it triggers an alert to assist abnormality identification

Approval

- Initial approval (Jan 2020)
  - Class II
  - Provided alerts for polyp detection without pinpointing the location
- Partial revision approval (Apr 2021)
  - Added rectangular box display for lesion localization and a speedometer to encourage optimal endoscope movement

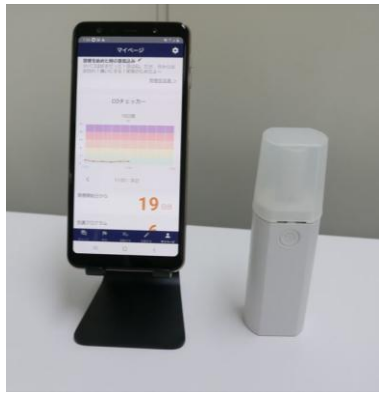
Reimbursement

- Initial status (2021):
  - A1 (All-inclusive): same points (~1,550pts≒$100) regardless of AI use. No incentive despite the software cost (1.5M JPY≒$9,500)
- "Challenge Application" (Feb 2022–Feb 2024):
  - Submitted peer-reviewed data of improved Adenoma Detection Rate
  - Evaluated as C2 (new ”functional category”)
  - Add-on 60pts (≒$4) can be added to when the AI assists in the detection and **subsequent surgery**

AMED https://www.amed.go.jp/en/news/release_20200129.html NetIB-News https://www.data-max.co.jp/article/39367
Cybernet https://www.cybernet.co.jp/company/about/news/press/2021/20210420.html

Example II. CureApp SC

Does this technology hold the same value as the technology that it referred to?



- Addresses psychological dependence on nicotine through AI-driven personalized messages and videos
- Patient app
- Portable CO checker: real-time measurement of carbon monoxide in breath
- Physician app: monitoring tool

Approval
- Aug 2020: Class II

Reimbursement
- Insurance listing (Dec 2020):
  - C2 (new “functional category”)
  - Fee Structure:
    - Add-on for “Program Guidance Fees”:
      - 140pts (Instruction on system use; $9)
    - System add-on fee:
      - 2,400pts (Covers the cost of the software/device; $151)
  - Reference device:
    - Implantable neurostimulators
      - For patients with implanted neurostimulation systems in the brain, spinal cord, or vagus nerve, for home-based management of chronic pain, tremors, or epilepsy

PMDA https://www.pmda.go.jp/medical_devices/2020/M20200911001/230909000_30200BZX00271000_C100_1.pdf
MHLW https://www.mhlw.go.jp/content/12404000/000693018.pdf

Summary: Challenges and opportunities

1. Structural fiscal pressure

- Rising healthcare expenditures, driven by aging, are sustained by premiums from the working-class, taxes, and national bond issuance
- Operational inefficiencies due to a historically fragmented insurers that the government is attempting to harmonize

2. Dilemma of price setting

- While medical services, drugs, and devices are priced via the fee schedule, the system is caught in a "pincer movement" between two opposing forces:
  - Macro-level: National pressure to restrict healthcare spending
  - Micro-level: Demands for higher points from healthcare providers and manufacturers due to inflation, rising wages, and material costs
- Whether the current pricing scheme is "appropriate" remains a subject of debate

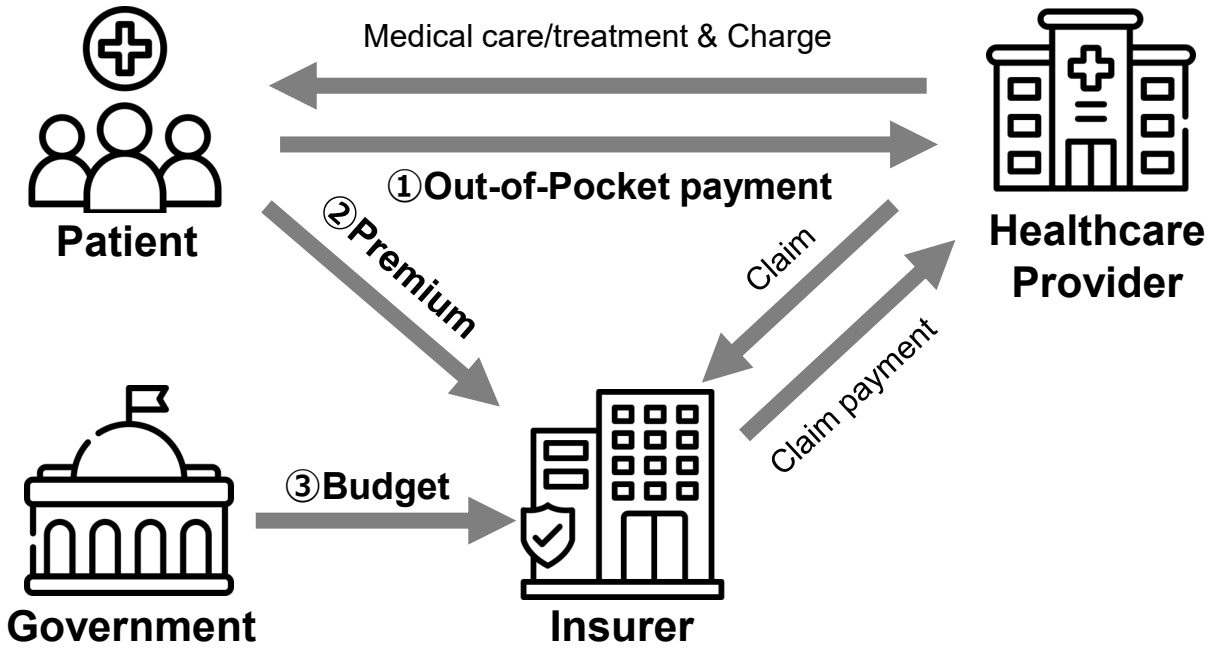
3. Role and reality of AI medical devices

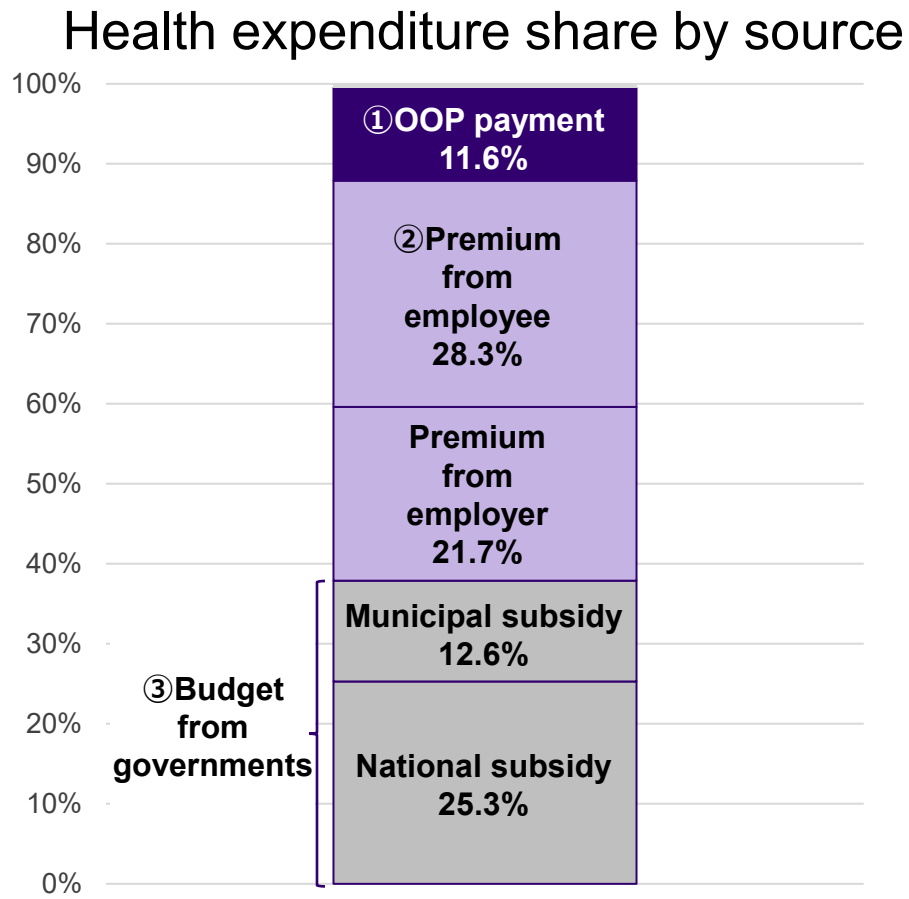
- AI medical devices hold the potential to address regional labor shortages and contribute to cost containment
- However, many cases are difficult to fit into existing regulatory and value-assessment frameworks
- Currently, decisions are being made on a case-by-case basis as regulatory updates and infrastructure developments remain very much a "work in progress."

Thank you for your attention!

Appendix

Health expenditure by budget source





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