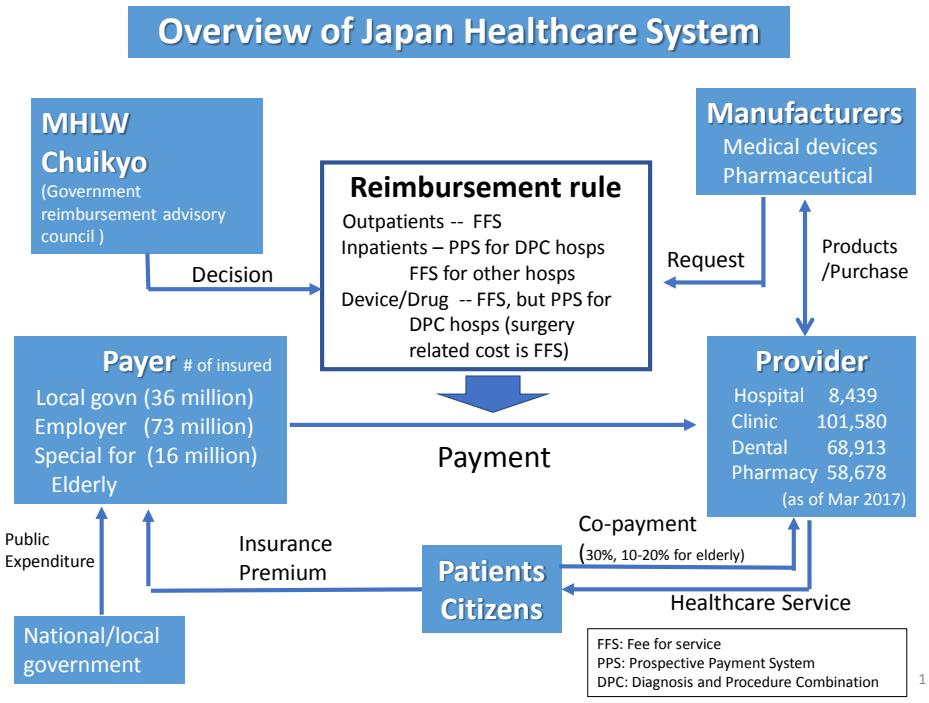
Current reimbursement policy on medical device in Japan and its challenges

Makoto Tamura, Ph.D
International University of Health and Welfare
Healthcare System Planning Institute



Two types of reimbursement rule for medical devices

STM (Special Designated Treatment Material

Prices individual medical devices, for example, implant and disposal device types such as pacemakers and artificial joints

Non-STM (non-special Designated Treatment Material)

Incorporates price as part of the technical fee for diagnostic devices such as CT/MRI scanners, or medical devices to be used repeatedly

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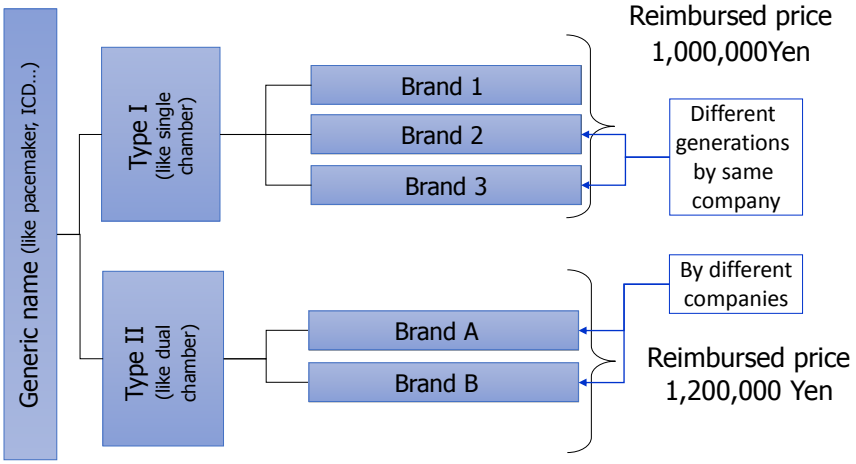
Medical Device reimbursement for STM
--Functional category system--



- **Reimbursement price is defined by each category**
- **200K product items are listed in 1,200 categories**

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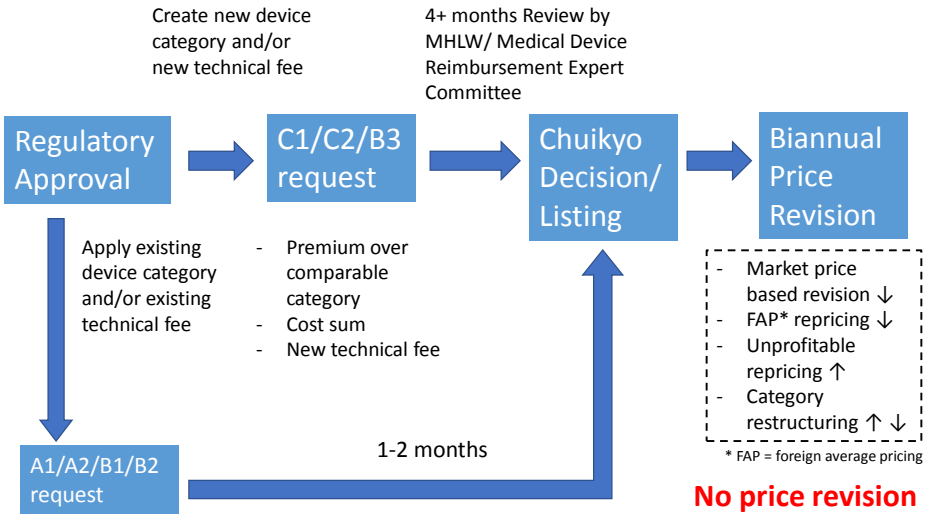
Medical Device Reimbursement Listing/Revision process



No price revision method based on efficacy data

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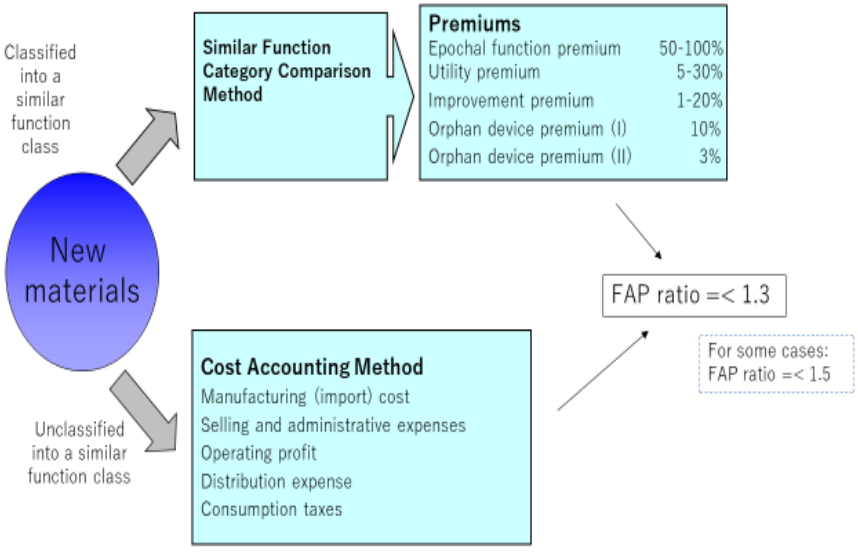
Rule for creating a new category (STM)



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Existing policies to ensure patients' early access to advanced technology

- Advanced Medicine (Senshin Iryo)
  - ✓Hospitals can request the government to apply "Advanced Medicine" when 1) the technologies (device, drug and others) have regulatory approval, but not fully reimbursed due to off-label use and other reasons, 2) the technologies are not regulatory approved yet
  - ✓When it is accepted, hospitals can charge the cost of new technologies to patients, and get reimbursement of related fees from NIH (national health insurance)
  - ✓Hospitals need to collect evidence based on protocol, and the data will be used for future discussion on reimbursement

- Health Technology Evaluation Proposal (Iryo Gijyutu Hyoka Teian)
  - ✓Academic societies can request to introduce new technical fees or increase existing fees every other years
  - ✓With this rule, hospitals/manufacturers would accept existing fees for new technologies at the beginning, and would try to increase those fees with evidence creation later on

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An Issue of Japan Medical reimbursement rule

- Reward for innovation is not given when the clinical efficacy data is not ready
  - ➢For instance, Bioresorbable Vascular Scaffold could not show its real characteristics until the three year after of the implant
- However, STM reimbursement price cannot be increased even if the efficacy data is provided after reimbursement listing
- To reduce device lag (regulatory approval timing difference between Japan and overseas), regulatory agencies have given approvals with less efficacy data
  - ➢Recently, the government seems to feel efficacy data is not enough for reimbursement listing in some cases

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New rule “Challenge Application”

- New rule, “Challenge Application” was introduced on April of 2018 (only for STM)
- Manufacturers can submit efficacy/safety (clinical) data to request new functional category (premium) after reimbursement listing
  - To do this, manufacturers have to get pre-approval from Medical Device Reimbursement Expert Committee at the time of initial listing
- The detail is not fixed yet on this rule, so the government and industry should discuss how this new rule work effectively
  - Regarding the detail of the rule, what kind of information should be given to the expert committee, the exact process to request challenge application and others are not known