APACMed
The voice of MedTech

Advancing SaMD Innovation in Japan:

APACMED'S POLICY RECOMMENDATIONS FOR REIMBURSEMENT REFORM

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EXECUTIVE SUMMARY

Advancing SaMD Innovation in Japan:
APACMed's Policy Recommendations for Reimbursement Reform

Software as a Medical Device (SaMD) represents a transformative opportunity for Japan's healthcare system. By improving accuracy, efficiency, and decision-making, SaMD can alleviate labor pressures, enhance care quality, and optimize resources. However, realizing these benefits depends on a reimbursement system that reflects SaMD's unique characteristics.

Japan has taken commendable steps through initiatives such as **Dash for SaMD 2 (2023)** and the **FY2024 Health Insurance Medical Materials System Reform**. These reforms mark progress, but additional measures are needed to ensure predictability, incentivize diffusion, and sustain innovation.

Key Challenges

- **Uncertainty in reimbursement classification**
  Current C2 and "Additional" categories lack clarity, limiting predictability for investment and market entry.

- **Low diffusion incentives**
  SaMD's marginal manufacturing costs make broad adoption critical, yet reimbursement does not adequately reward efficiency gains such as reduced physician workload.

- **Rigid facility eligibility standards**
  Requirements often fail to reflect how SaMD enables care delivery with fewer or differently qualified staff.

- **Evidence generation burden**
  Clinical trial expectations are disproportionate to SaMD's typically incremental but significant benefits, slowing updates and access.

APACMed's Recommendations

1. **Strengthen Predictability**
- Clarify and standardize reimbursement categories for SaMD.
- Publish practical guidance and case studies to improve transparency.
- Maintain structured dialogue with industry to adapt to emerging delivery models.

2. **Incentivize Diffusion**
- Apply premium reimbursement where SaMD reduces clinician workload, supporting Japan's workstyle reform goals.
- Address hospitals' financial constraints by accelerating incentives for adoption.

3. **Modernize Facility Eligibility Standards**
- Relax requirements where SaMD ensures equivalent or improved safety and effectiveness with fewer or differently trained staff.
- Proportion evidence requirements to societal benefit, avoiding unnecessary costs and delays.

Call to Action

APACMed applauds Japan's leadership in advancing SaMD policy and is committed to working with government and healthcare stakeholders. By strengthening predictability, incentivizing diffusion, and modernizing eligibility standards, Japan can:

- Expand access to innovative digital health solutions.
- Enhance system efficiency and workforce sustainability.
- Position itself as a global leader in SaMD innovation.

APACMed stands ready to partner with policymakers to create a future where SaMD innovation benefits patients, providers, and society at large.

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INTRODUCTION

At APACMed, we believe that digital health innovation, and in particular Software as a Medical Device (SaMD), has the potential to transform healthcare delivery in Japan. Healthcare is a labor-intensive sector, and rising costs are placing pressure on systems worldwide. SaMD can play a critical role in alleviating these pressures by enhancing efficiency, accuracy, and clinical decision-making across the care continuum.

Unlike tangible medical devices, SaMD carries high development and regulatory costs but negligible marginal manufacturing costs. Its greatest societal benefit is realized when adoption is widespread. To achieve this, reimbursement systems must evolve to recognize SaMD's unique characteristics and to create an environment where patients, healthcare professionals, payers, and manufacturers alike can benefit from its innovation.

In Japan, **Software as a Medical Device (SaMD)** approvals have been steadily increasing, averaging **20 to 40 new products each year,** with a cumulative total of **268 approved products as of September 2024** (PMDA). The largest share of these approvals falls under **advanced medical devices**, many of which have been approved **without the need for clinical trials**. However, the number of advanced devices supported by **clinical trial data** is gradually rising, reflecting a shift toward stronger evidence generation.

A notable trend is the **rapid expansion of AI-driven SaMD**, particularly in **diagnostic support applications** such as **CT, MRI, X-ray, endoscopic imaging, electrocardiogram, and ultrasound** analysis. These developments highlight Japan's proactive regulatory environment and growing expertise in AI-enabled healthcare technologies.

As this field matures, Japan is now entering a critical phase of **establishing precedents and cost frameworks** for **socially verifying the value and benefits** of SaMD — ensuring that innovation translates into measurable healthcare impact.

This position paper sets out APACMed's views on the role of Japan's reimbursement system, highlights gaps in current frameworks, and offers recommendations to ensure SaMD innovation thrives while strengthening Japan's role as a global leader in digital health.

THE ROLE OF REIMBURSEMENT SYSTEMS

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Reimbursement policies are a cornerstone of healthcare systems, shaping access, sustainability, and innovation. In Japan, the universal insurance system and the deliberations of the Central Social Insurance Medical Council (Chuikyo) ensure nationwide consistency in coverage and pricing.

APACMed recognizes five critical functions of reimbursement systems:

1. **Sustaining healthcare financing**
   Balancing affordability with innovation through transparent price-setting.

2. **Providing endorsement through insurance coverage**
   Validating technologies' societal and clinical value.

3. **Enabling predictability for investment**
   Encouraging long-cycle, high-cost innovation by ensuring manufacturers can recover R&D.

4. **Incentivizing clinical adoption**
   Driving hospitals and clinics to invest in and adopt new technologies.

5. **Supporting global competitiveness**
   Allowing Japan to remain an attractive market for innovation and a contributor to global standards of care.

RECENT POLICY DEVELOPMENTS

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APACMed welcomes recent steps taken by Japanese authorities to promote SaMD adoption:

- Dash for SaMD 2 (2023): A strategic package to accelerate commercialization of SaMD.
- FY2024 Health Insurance Medical Materials System Reform: A milestone reform reflecting SaMD's growing role in healthcare.

These initiatives demonstrate commendable government leadership and an openness to dialogue with industry. However, challenges remain in aligning reimbursement policies with the realities of SaMD development, adoption, and diffusion.

CHALLENGES UNIQUE TO SAMD

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APACMed emphasizes that SaMD differs fundamentally from traditional medical devices and requires tailored reimbursement approaches:

- **Non-physical mechanisms of effect:** SaMD's value often lies in behavioral, cognitive, or process efficiency improvements.
- **Low marginal manufacturing costs:** Societal utility increases with scale, underscoring the need for diffusion incentives.
- **Rapid iteration cycles:** Rigid approval and reimbursement processes risk delaying updates and improvements.
- **Mild but cumulative effects:** Evidence generation is costly relative to expected reimbursement, creating investment risk.
- **Global competitiveness:** Uncertain reimbursement timelines discourage early launches in Japan, potentially limiting patient access.

Here is an example of accuracy improvement. Accuracy improvement leads to detection of lesions that can be missed even by specialists, and to a higher level than has already been achieved by investing human resources of specialists.

It is generally said that the evolution of things follows an S-shaped growth. In imaging diagnosis, improvement in the interpretation accuracy of specialists can be said to be an event in which the slope of improvement has already become slack. How to deal with them is the role of policy.

Examples of improved accuracy

Treatment and diagnosis content effect

1. Improved detection rate of abnormal breast mammography findings
2. Improved accuracy of chest X-ray lesion detection by specialists
3. Decreased variability in chest CT lesion size reading
4. Decreased preoperative simulated blood loss
5. Decreased ICU monitoring mortality hazard ratio

- Data submitted by industry associations at the 3rd Program Medical Devices Working Group in FY 2023.
- FY 2023 3rd Program Medical Device Specialist Working Group Based on data submitted by industry associations. https://www.mhlw.go.jp/content/12404000/001097527.pdf

APACMED'S RECOMMENDATIONS

To fully realize SaMD's potential, APACMed calls for three priority reforms:

6.1 Strengthen Predictability

- Provide clearer, more consistent criteria for C2 and "Additional" reimbursement categories.
- Publish enhanced administrative guidance, including FAQs and case studies, to increase transparency.
- Ensure ongoing dialogue with industry to capture evolving delivery models.

6.2 Incentivize Diffusion

- Apply premium reimbursement where SaMD demonstrably reduces healthcare professional burden, particularly as Japan advances workstyle reforms.

- Recognize that hospitals face financial constraints, and design reimbursement to accelerate adoption despite capital limitations.

What is important here is policy guidance with a view to the future of medical practice. Under current insurance coverage, there is a tendency to favour rigorous measurement data. In light of this, the medical device industry has also shown quantitative reductions in the burden on physicians. Based on mammography, X-ray, and CT images, the industry has shown comparisons of diagnostic imaging interpretation time, accuracy compared with specialists, and accuracy compared with non-specialists. Overall, reductions of 10% to 20% have been achieved, and accuracy has also improved.

Examples of time reductions

Treatment and diagnosis content effect

6. Breast mammography interpretation time reduced by 13%
7. Breast mammography interpretation time reduced by 22%
8. Chest CT lesion size measurement time reduced by 63%
9. Bone density measurement area designation time reduced by 20%

FY 2023 3rd Program Medical Device Specialist Working Group Based on data submitted by industry associations.

6.3 Modernize Facility Eligibility Standards

- Allow flexibility where SaMD enables safe delivery of care with fewer or differently qualified staff.
- Streamline evidence requirements so they are proportionate to the societal benefit of SaMD adoption.
- Create mechanisms to validate evidence reliability without excessive cost or delay.
- Is it necessary to add more than just from the perspective of fiscal neutrality if it contributes to reducing health care access imbalances?

Examples of time reductions

Treatment and diagnosis content effect

10. Improvement of chest X-ray lesion detection accuracy by non-specialists compared with specialists
11. Reduction in re-planning of radiotherapy treatment plan

- Data submitted by industry associations at the 3rd Program Medical Devices Working Group in FY 2023.
- FY 2023 3rd Program Medical Device Specialist Working Group Based on data submitted by industry associations. https://www.mhlw.go.jp/content/12404000/001097527.pdf

7 CONCLUSION

APACMed applauds the Japanese government's leadership in advancing SaMD policies and its willingness to collaborate with industry stakeholders. SaMD is uniquely positioned to optimize healthcare delivery by reducing input costs while maintaining high-quality outcomes.

We urge policymakers to strengthen predictability, incentivize diffusion, and modernize eligibility standards to accelerate SaMD adoption. By doing so, Japan will not only enhance access and efficiency for its own healthcare system but also cement its position as a global leader in digital health innovation.

APACMed stands ready to work in partnership with government, industry, and healthcare stakeholders to realize this shared vision.

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About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit **www.apacmed.org**