

APACMed, the voice of medtech in the Asia Pacific, launched its [Digital Health Committee](#) in 2020, which included a specific focus on improving reimbursement levels of novel interventions in the region. In 2021, APACMed [published its landmark report \(available in Japanese\)](#) outlining the call-to-action for Digital Health reimbursement, leading to the creation of the Digital Health Reimbursement Alliance (DHRA) in 2022. Now formalized, the DHRA is a multi-stakeholder body which convenes regularly for knowledge sharing and collaboration.

Of key importance for the DHRA is country-level activation, which is achieved through bespoke public-private forum discussions. The [first session](#) was held in Korea in March, with a [second session](#) occurring in Japan in June, featuring guests of honour Dr. Kohkichi Morimoto of Keio University School of Medicine and Makato Tamura of the International University of Health and Welfare's Medical Technology Policy Institute, supported in dialogue by Tomohiro Watanuki from Medtronic and Jun Sekiguchi and Danny Risberg from Baxter. Getting reimbursement right in Japan is critical, as the country accounts for some 10% of the global medical device industry and is witnessing local market value of Digital Health growing by north of 30%. The purpose of this write-up is to summarize the high points from the discussion, as well as to frame the outlook for next steps ahead. You can access the full recording [available here](#).

## Takeaway #1: Understanding how Digital Health reimbursement policies function in Japan

Sekiguchi-san began the session by explaining the latest trends in Digital Health reimbursement in Japan, which has indeed been making traction. In fact, there have already been four such approvals in the country over the recent period. Recent policy enhancements are now able to distinguish Software as a Medical Device (SaMD) from traditional medical devices by level of risk classification.

Importantly, of course, are the associated reimbursement fee schedules for more novel interventions like SaMD. To the right is a snapshot of the presentation from Sekiguchi-san ([full slides are available online](#)), which demonstrate optionality in terms of utilizing the existing package schemes, newer standalone fee schedules which can accommodate Digital Health, and even the ambition for more integrated reimbursement tying Digital Health to broader payment reform along the healthcare continuum.

According to Sekiguchi-san, the reimbursement bodies are also looking at Digital Health which deliver holistic impact to the health system, such as solutions which reduce care provider workload. **There will always be a trade-off between the risk level of the intervention and the associated reimbursement**, he noted, **something which session stakeholders agreed requires ongoing discussion**.

Now, let us look at a recent example of success with the new scheme.

### 4. Government direction for SaMD reimbursement

Central Social Insurance Medical Council (Chuikyo) announced below criteria for the reimbursement of SaMD for 2022 reimbursement revision.

#### イ プログラム医療機器の評価について

- 医療機器該当性のあるプログラム医療機器については、当該製品の特性に応じて、
  - ・ 技術料に平均的に包括して評価されるもの
  - ・ 特定の技術料に加算して評価されるもの
  - ・ 特定の技術料に一体として包括して評価されるもの
  - ・ 特定保険医療材料として評価されるもの
- また、プログラム医療機器の特性から、医師の診療をサポートすることで、より少ない医療従事者で同等の質が確保できること等があり得ることから、プログラム医療機器の評価に当たっては、医師の働き方改革の観点を念頭に置きつつ、それぞれの製品の特性を踏まえ、施設基準等への反映も含め評価する。

Reimbursement evaluation of Medical Device Software (SaMD) will be done in one of the followings;

1. Generally included in overall technical fee
2. Added onto specific technical fee
3. Included in specific technical fee
4. Separately reimbursed as STM\*

Assessment will be done at Chuikyo expert panel upon application by the manufacturer of device.

\*STM: Specially Treated Medical Device

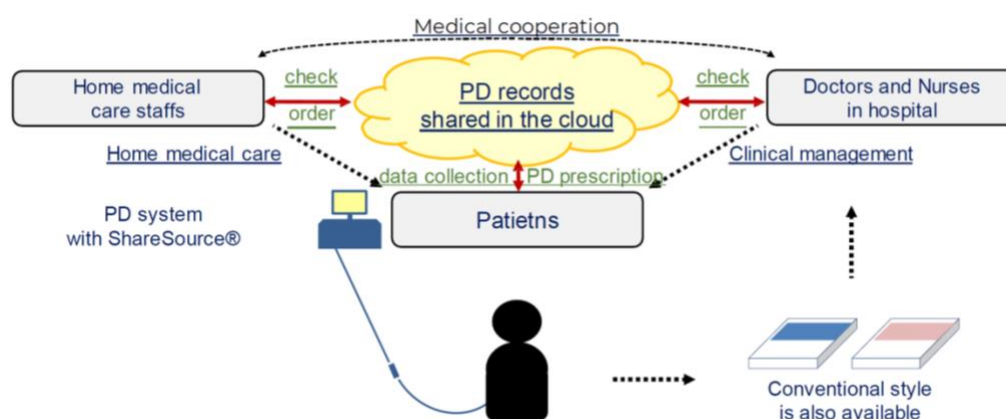
Therapy supporting software that will reduce HCP workload may be evaluated through medical institution standard (施設基準).

## Takeaway #2: Lessons learned from a real-world use case (peritoneal dialysis)

Kokichi-san, physician expert in the field of dialysis therapy, provided an overview of how ShareSource, a cloud connectivity platform for peritoneal dialysis, received reimbursement approval in 2022 under the new scheme. The reimbursement shift is part of a broader trend to support dialysis patients in the comfort of their own home, albeit while staying in close contact with the care provider. A clinical trial was conducted in Japan to confirm the cost-benefit of using a platform like ShareSource, in terms of clinical outcomes as well as socioeconomic impact in areas like care provider productivity and reduced hospitalizations. ShareSource is

the first Digital Health solution for dialysis patients which is reimbursed in Japan. A key demonstration of the solution in Kokichi-san's presentation is below, with the full presentation incorporated into the session pack link shared above.

Stakeholders in the session then reflected on the implication of this example, as well as the few other examples which had preceded it in Digital Health reimbursement in areas such as cardiovascular and respiratory management. What is really unique, the stakeholders claim, is that **reimbursement recognizes interventions beyond the device and into the service**. There is exciting fervour that these examples, as they gather data and evidence over time, will open the door for more Digital Health solutions to be reimbursed in Japan going forward.



## Takeaway #3: Multi-stakeholder views about what the path forward looks like from here

While there is a degree of optimism amongst session stakeholders for Digital Health in Japan, they recognize that we are only at the beginning of a long journey ahead. We must gather more data about the impact of deploying Digital Health solutions and how these fit into the bigger picture of healthcare reform, such as in the case of the

shift to home dialysis. This means **continual alignment to the national health strategy of Japan**, in order to ensure the country supports its patients while also staying competitive in the global ecosystem.

Lastly, session stakeholders recognized the **need to bring others to the table for discussion** too, like drug companies to leverage data from Digital Health to better understand drug interactions. The goal, according to the concluding remarks at the session, is to strive for “economically-sustainable Digital Health through reimbursement”.



If you are interested in joining the dialogue, please do reach out to [rsarno@apacmed.org](mailto:rsarno@apacmed.org)! We are planning another country-level discussion during July-August (to dive into the Australian context), and will then host a break-out track at the [APACMed MedTech Forum](#) taking place in September.



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