APACMed Digital Health Reimbursement Policy Forum

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Introduction

The APACMed Policy Forum on Digital Health Reimbursement was held on 23 May 2023, with participants from Australia, Japan, Singapore, South Korea, Germany, France, and the UK. Several digital health policymakers, academicians, and experts from the respective countries, along with the APACMed Digital Health Reimbursement Alliance (DHRA) core committee, local trade associations, and EVERSANA members participated in the event.

The forum was structured across three sessions:

Session 1: Background on the digital health landscape across APAC, US, and Europe

Session 2: Key learnings from APAC and Europe in the digital health reimbursement area

Session 3: Scenario-based case discussion on an imaginary digital therapeutic product

The policymakers shared the current status and upcoming priorities relative to digital health reimbursement in their jurisdictions.

Additionally, the participating members from Australia, Japan, Singapore, and South Korea provided valuable perspectives on the reimbursement frameworks through their feedback on the likelihood of reimbursement for the imaginary digital therapeutic product across different scenarios.

Through the APACMed DHRA Policy Forum, APACMed, with the support of EVERSANA, aimed to create a baseline understanding of the reimbursement status for digital health technologies in AU, JP, SG, and KR. The digital readiness of these markets was compared with several advanced markets such as the U.S., DE, FR, and the UK, which have made considerable advances in reimbursing digital health technologies through establishing reimbursement frameworks suited to their country's evolving requirements.

Policymakers from the four markets were invited to discuss the progress made in deciphering the complex reimbursement pathway for digital health and the outstanding challenges that make it hard to bring new innovations swiftly into the market and increase access to patients via reimbursement.

This paper provides a high-level view for industry players and payers of where their individual markets stand in terms of reimbursement policies for digital health and the challenges that complicate the process of funding and reimbursing such technologies from the payer's perspective. In addition, it provides a close-up view of what policymakers may look for when assessing a digital health technology for reimbursement in terms of clinical and economic evidence.

Executive Summary

Presently, most APAC markets believe that reimbursement of digital health technologies is at the beginning or intermediate stage, and some recognize the need to establish a fit-for-purpose framework.

This forum demonstrated that, although digital health technologies are gaining momentum across APAC, reimbursement pathways remain unclear. Learnings from Germany, France, and the UK, have further emphasized the pressing need for continuous engagement among various stakeholders to keep the topic of digital health reimbursement in the spotlight and ensure that critical multi-stakeholder discussions take place.

Digital health technologies are gaining traction across APAC. However, reimbursement pathways remain complex and unclear:

Across all 4 APAC countries				
• Clinical evidence – RCT and RWD are highly valued. • The patient voice is relatively quiet. • Reimbursement pathways are unclear. • Focus should be on those patient segments where evidence is strong. • There is no Coverage with Evidence Development (CED).	• A different framework is unlikely to be prioritized. • Several technologies are already covered by hospitals. • Funding options exist. • Seamless integration into hospital systems and aligning with country strategy is key.	• Some digital technologies are covered. • Digital health technologies, if adjuvant therapies, are not covered. • Cost savings continue to have a higher weight for reimbursement.	• Several digital technologies are covered under a medical device framework or territory funding. • The Medical Services Advisory Committee would look at the totality of evidence and not just the "unmet clinical need" to make a decision.	• A few digital therapeutics (DTx) are covered (unlike other geographies). • Clinical benefits are more important than economic benefits under the current universal national insurance scheme.

Digital Health

- User-facing technologies
- Health information technology
- Consumer health information
- Telehealth
- Decision support software
- Enterprise support
- Clinical care administration and management tools

Digital Medicine

- Digital diagnostics
- Digital biomarkers
- Electronic clinical outcome assessments
- Remote patient monitoring
- Decision support software
- Robotics surgery
- Digital companion
- Digital products that both measure and intervene, and do not require human intervention to serve their primary purpose

Digital Therapeutics (DTx)

Software that delivers therapeutic interventions such as:

- Treat a disease: DTx that deliver a medical intervention to treat a disease
- Manage a disease: DTx that deliver a medical intervention to manage a disease
- Improve a health function: DTx that deliver a medical intervention to improve health function and/or prevent a disease

The importance of the patient voice in reimbursement has yet to be actualized, as has been the case for pharmaceuticals and devices. For this to happen, clear quantification methods will be needed.

Introduction to Digital Health

The term Digital Health covers a broad set of scientific concepts and technologies, including genomics, big data, artificial intelligence, 3D printing, Software as a Medical Device (SaMD) and digital therapeutics (DTx), mobile health, virtual and augmented reality, robotic surgery, analytics, wearables, biosensors, companion diagnostics, mobile applications, and telemedicine.[1]

Reimbursement of Digital Health Technologies in Select Non-APAC Countries

GERMANY

In Germany, the Digital Health Care Act (Digitale-Versorgung-Gesetz or DVG) was passed in November 2019. It describes the formalization of the DiGA, which can be prescribed by physicians and psychotherapists or reimbursed directly by sickness funds upon request of insured persons provided the corresponding diagnoses were made by the physician. DiGA may include standard software, software as a service, mobile as well as browser-based applications.

To be included in the DiGA list, apart from meeting basic requirements such as safety, data protection, and interoperability, manufacturers must prove that the app has a positive effect on patient care. The manufacturer should present a scientific evidence-based evaluation through clinical trials by improving the user's health. If the assessment is successful, the product can then be included in the DiGA list. If the evidence to demonstrate a positive effect on care is not available yet but the other requirements are fulfilled, a manufacturer can apply for the provisional inclusion in the DiGA list and can complete the necessary study within 12 months in a trial phase.

Thus, there are two levels of DiGA approval: provisional and permanent. As of July 2023, of the 47 DiGA-listed apps, 20 are permanent and 27 are provisional. Six apps have been delisted.

Select Examples (non-exhaustive)

Examples of Digital Health Technologies Reimbursed In Germany					
Product	**Manufacturer**	**Classification of digital health solution**	**Use case**	**Digital health component**	**Customer/ payer type**
Deprexis	Gaia health	Digital therapeutic	CBT based self-help app for depression	Mobile health app	Public payer
Elevida	Gaia health	Digital therapeutic	CBT based app for multiple sclerosis patients who are fatigued	Mobile health app	Public payer
Selfapy's online course in depression	Selfapy	Digital therapeutic	Online course (CBT based) for depression	Mobile health app	Public payer
Invirto	Sympatient	Digital therapeutic	CBT based app for agoraphobia and panic disorder	Mobile health app	Public payer
Velibra	Gaia health	Digital therapeutic	CBT based app for anxiety and panic disorders	Mobile health app	Public payer
Kalmeda	Mynoise	Digital therapeutic	Therapy for chronic tinnitus	Mobile health app	Public payer
Zanadio	Aidhere	Digital therapeutic	App based on multimodal conservative obesity therapy for female patients	Mobile health app	Public payer
Hedy System	Implicity	Digital health	Remote patient monitoring for patients with heart failure	Coupled with digital health app	Public payer
Brain+	Brain+	Digital therapeutic	Cognitive stimulation therapy app for dementia – helps caregivers easily deliver therapy*	Mobile health app	Public payer

*DiGA apps (non-exhaustive) *DiPA are digital care/nursing applications, for which the ordinance and reimbursement guidelines were published in 2022. It is open to submissions, and BfArM is expected to announce the list in 2023. Brain+ is one of the apps expected to qualify, along with Care Predict at Home and Nui Pflege.*

Reimbursement for teleconsultation: During the coronavirus pandemic, there was no limit to the number of online consultation hours for remuneration. However, since April 2022, the number of cases and volume of services have again been capped at 30%.

FRANCE

In France, a positive reimbursement for medical devices requires inclusion in the LPPR (List of Reimbursable Products and Services) list and a sufficient actual medical benefit as assessed by CNEDiMTS (Medical Device and Health Technology Evaluation Committee) prior to inclusion.

As of April 2023, France has implemented an early coverage process for Digital Medical Devices (DMDs) or remote medical monitoring activities called PECAN (prise en charge anticipée des dispositifs médicaux numériques). Similar to Germany's DiGA, it introduces a one-year special coverage by the French health care system for solutions demonstrating sufficient clinical and/or organizational benefits.

Select Examples (non-exhaustive)

Examples of Digital Health Technologies Reimbursed In France					
Product	**Manufacturer**	**Classification of digital health solution**	**Use case**	**Digital health component**	**Customer/ payer type**
Diabnext	Glooko	Digital medicine	Fully automated digital diabetes management app that automatically monitors insulin and blood glucose.	Mobile health app	Public payer (Telemonitoring list)
Satelia Cardio	Satelia	Digital medicine	Allows remote monitoring of cardiac failure patients and helps prevent cardiac decompensation and reduce hospitalizations	Mobile health app	Public payer (ETAPES program)
DBLG1 system	Diabeloop	Digital health	Automates and personalizes the treatment of Type 1 diabetes	Coupled with digital health app	Public payer (LPPR List)
Minimed 780G	Medtronic	Digital health	Insulin pump system with SmartGuard automation for self-adjusting basal delivery with autocorrection dosing.	Coupled with digital health app	Public payer (LPPR List)
Moovcare	Moovcare	Digital therapeutic	Telemonitoring of lung cancer patients for detecting relapse or complications during follow-up	Mobile health app	Public payer (LPPR List)
Diabeo	Sanofi	Digital therapeutic	A telemedicine solution that allows real-time monitoring of basal-bolus insulin therapy as well as therapeutic decision-making, integrating both basal and bolus dose calculation	Mobile health app	Public payer (Telemonitoring list)

UK

The funding mechanism has been continuously evolving. While local NHS organizations play a major role in funding and reimbursing digital health solutions, centralized funding for digital health technologies remains a work in progress.

In 2016, a national reimbursement pathway called the Innovation and Technology Tariff (ITT) was introduced to remove the need for multiple local price negotiations. In 2019, the Innovation and Technology Funding Payment (ITP) was added to the ITT program. It provided national reimbursement, with a single national price, for devices/technologies that have already proved their clinical effectiveness and are ready to be rolled out nationally. The Med Tech Funding Mandate (MTFM), introduced in April 2021, builds on the ITP program. To be included, technologies must be effective (with positive NICE MTGs/DGs), be cost-saving over three years, and have a budget impact that does not exceed £20 million in any of the first three years.

USA

The U.S. healthcare reimbursement system is a mix of public and private third-party coverage. 70% of commercial health plans under Integrated Delivery Network (INDs), Managed Care Organizations (MCOs), and Pharmacy Benefits Managers (PBMs) either provided or planned to consider DTx programs for coverage in 2021. In the public insurance market, most Medicare Advantage, Prescription Drug Plan (PDP), and Managed Medicaid-based health plans consider dedicated reimbursement for DTx programs.

Select Examples (non-exhaustive)

Examples of Digital Health Technologies Reimbursed In the UK

Product	Manufacturer	Classification of digital health solution	Use case	Digital health component	Customer/ payer type
Oviva	Oviva	Digital health	Diabetes support program	Mobile health app	Partnerships with regional NHS payers
Medelinked	Medelinked	Digital health	Online Patient health record management platform for providers	Mobile health app	ITT
Heartflow FFRCT	Heartflow	Digital medicine	3D imaging to diagnose patients with suspected coronary artery disease	AI based software	ITP
KardiaMobile	AliveCor	Digital health	Remote heart monitor KardiaMobile that records electrocardiogram on a smartphone	Coupled with digital health app	NHS
myCOPD	MyMHealth	DTx	App to help manage chronic lung disease	Mobile health app	ITT
Sleepio	Big Health	DTx	CBT based app for insomnia	Mobile health app	NHS*

**Free for NHS patients in the Thames valley*

Select Examples (non-exhaustive)

Examples of Digital Health Technologies Reimbursed In the US					
Product	**Manufacturer**	**Classification of digital health solution**	**Use case**	**Digital health component**	**Customer/ payer type**
BrainCheck	BrainCheck	Digital health	It provides comprehensive cognitive and behavioral health assessments, and clinical decision support to health providers	Mobile health app	Public & private
CureMatch	CUREMATCH	Digital health	A decision support system which provides oncologists with clear, accessible, predictive treatment analysis to equip them with actionable knowledge tailored for each unique case	AI based software	Public & private
Aidoc	Aidoc	Digital health	A decision support system to the clinicians in the field of radiology, cardiology and neurology	AI based software	Public & private
Ava bracelet	AVA	Digital health	It tracks 5 physiological signals and identifies fertile days using machine learning algorithms	AI based wearable sensor	Private payer
FreeStyle Libre 2	Abbott	Digital health	Integrated continuous glucose monitoring (CGM) system for patients with diabetes	Coupled with digital health app	Public (CMS) & private
RelieVRx	AppliedVR	DTx	It is the first and only FDA-authorized at-home immersive virtual reality (VR) pain treatment indicated as adjunctive treatment for chronic lower back pain	VR software	Public & private
reSET & reSET-O	Pear Therapeutic	DTx	reSET and reSET-O are intended to provide cognitive behavioral therapy for substance use disorder and opioid use disorder respectively	Mobile health app	Public & private
Somryst	Pear Therapeutic	DTx	Somryst provides neurobehavioral intervention for patients with chronic insomnia	Mobile health app	Public & private
EndeavorRx	Akili interactive	DTx	Video game treatment to improve attention function in children with ADHD	Mobile health app	Private payer

CMS: Centers for Medicare & Medicaid Services

Reimbursement of Digital Health Technologies in Select APAC Countries

SINGAPORE

In Singapore, the reimbursement pathway for Digital Health and Medical devices is currently the same. All devices need to be included in the Medical Technology Subsidy List (MTSL) to receive reimbursement or public subsidy.

KOREA

While there is currently no digital health-specific reimbursement pathway, through the Innovative Health Technology system, digital health technologies can receive temporary reimbursement/ government subsidies as medical devices.

Select Examples (non-exhaustive)

Examples of Digital Health Technologies Approved or Privately Funded in Singapore					
Product	**Manufacturer**	**Classification of digital health solution**	**Use case**	**Digital health component**	**Customer/ payer type**
Mydoc	MyDoc	Digital health	Company-facing employee health benefit program	Mobile health app	Private payer (employee health benefit program)
Naluri	Naluri	Digital health	Digital health coaching program with a focus on mental well-being	Mobile health app	Private payer
Selena +	EyRIS	Digital medicine	A deep learning system (DLS) to screen diabetic eye disorders	AI based software	Approved but not reimbursed
reSET system	Pear therapeutics	DTx	Treatment of adults with substance use disorder	Mobile health app	Approved but not reimbursed

Select Examples (non-exhaustive)

Examples of Digital Health Technologies Approved or Reimbursed in Korea					
Product	**Manufacturer**	**Classification of digital health solution**	**Use case**	**Digital health component**	**Customer/ payer type**
FreeStyle Libre	Abbott	Digital health	Continuous glucose monitoring system	Coupled with digital health app	Public payer
Da Vinci Robotic Surgery	Intuitive Surgery	Digital health	Robotic Surgery	Robotic surgery software	Approved but not reimbursed
Space pump	B Braun	Digital health	Smart treatment	Coupled with medical device	Public payer
VNS Therapy System	Livanova	Digital health	Neuromodulation	Medical device	Public payer
Lunit Insight CXR	Lunit	Digital medicine	AI based medical imaging	AI based software	Approved but not reimbursed
AIHuB	JLK Inspection	Digital medicine	AI based medical imaging	AI based software	
Deep Lung, Deep Spine	Deepnoid	Digital medicine	AI based medical imaging	AI based software	
Somzz	Aimmed	DTx	CBT based app for insomnia	Digital health app	

The coverage decisions [2] for 2 Digital Health Technologies (DHTs) (long-term continuous electrocardiography and gait training care using robots in stroke patients) with the condition of re-evaluation in 3 to 5 years were made using traditional cost calculation methods that failed to reflect the characteristics and DHTs' value. Consequentially, reimbursed payments were lower due to the lack of a physician work component. These decisions were made despite concerns from the manufacturers.

Reimbursement for telemedicine:

Since COVID-19, the National Health Insurer (NHI) reimburses 80% of medical fees of telemedicine but this facility only covers COVID-19 medicine and consultation. Telemedicine providers include Doctor Now, Soldoc, Ollacare and Dr.Call.

AUSTRALIA

Recommendations of reimbursement of digital health products and services fall under the Medical Services Advisory Committee (MSAC) and Prostheses List Advisory Committee (PLAC). While MSAC makes funding recommendations on new procedures/ devices for MBS, NDSS and other programs, PLAC makes recommendations on whether to include new procedures/devices in the prostheses list.

JAPAN

Almost all medical devices sold in Japan are ultimately paid for by Japan's National Health Insurance (NHI) system. Reimbursement of digital health products comes under the traditional medical device framework, in which products are directly reimbursed by material fee (paid for the product) or indirectly reimbursed by technical fee (paid for the procedure).

Select Examples (non-exhaustive)

Examples of Digital Health Technologies Reimbursed in Australia					
Product	**Manufacturer**	**Classification of digital health solution**	**Use case**	**Digital health component**	**Customer/ payer type**
FreeStyle Libre	Abbott	Digital health	Glucose monitoring system	Coupled with digital health app	Patients/Public payer
Merlin@Home transmitter	Abbott	Digital health	Remote home monitoring	Medical device	Patients/Public payer/private insurers
myMerlin™	Abbott	Digital medicine	Software App communicates with insertable cardiac monitor	Coupled with digital health app	Patients/Public payer/private insurers
Dexcom G6 system	Dexcom	Digital health	Continuous Glucose Monitoring	Coupled with digital health app	Patients/Public payer/private insurers
TALi App	TaliHealth	DTx	Digital cognitive training program intended to improve attention function in neurodiverse children aged 3-8 years.	Mobile health app	Patients/Public payer/private insurers
VNS therapy system	Livanova	Digital health	Treatment-Neuromodulation	Medical device	Patients/Public payer/private insurers
VISIA AF MRI XT SureScan ICDs	Medtronic	Digital health	Digital single chamber implantable cardioverter defibrillator	Medical device	Private
Cochlear Baha 5 Sound Processor	Cochlear	Digital health	A digital sound processor for implantable bone conduction hearing systems.	Medical device	Private

MBS: Medicare Benefits Schedule; NDSS: National Diabetes Services Scheme

Select Examples (non-exhaustive)

Examples of Digital Health Technologies Reimbursed in Japan					
Product	**Manufacturer**	**Classification of digital health solution**	**Use case**	**Digital health component**	**Customer/ payer type**
Heartflow Analysis	Heartflow	Digital medicine	AI based imaging	AI based software	Public payer*
FreeStyle Libre	Abbott	Digital health	Continuous glucose monitoring system	Coupled with digital health app	Public payer**
Dexcom G6	Terumo	Digital health	Continuous glucose monitoring system	Coupled with digital health app	Public payer
Da Vinci Robotic Surgery	Intuitive Surgery	Digital health	Robotic Surgery	Medical device	Public payer
VNS Therapy System	Livanova	Digital health	Neuromodulation	Medical device	Public payer
CureApp SC	CureApp	DTx	App for nicotine addiction	Digital health app	Public payer
CureApp HT	CureApp	DTx	App for hypertension	Digital health app	Public payer

**Receives a technical fee, not a device payment **Sensors are reimbursed, not the digital component.*

Challenging reimbursement of medical device-associated software upgrades:

Japan currently does not offer additional reimbursement for a device that undergoes a software enhancement, i.e., upgraded software capabilities that can enhance a healthcare outcome using the same device are not offered higher reimbursement rates even if the product (with upgraded software) can replace other testing and could save costs for the healthcare system.

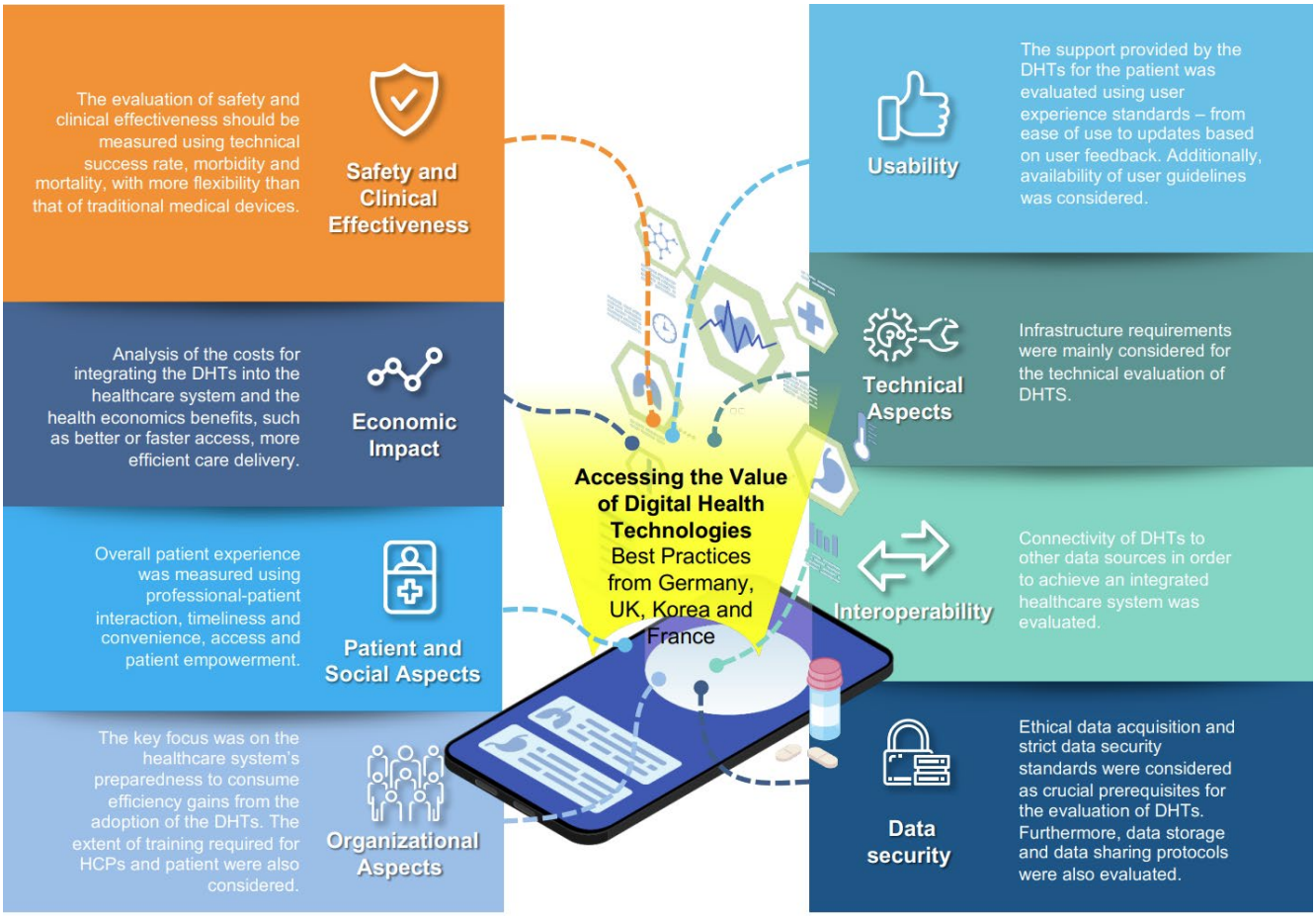
Reimbursement for telemedicine:

National health insurance reimburses 70% of medical fees. Telemedicine providers in Japan include MICIN and Medley.

Value Framework Proposed by APACMed for the APAC Region

While reimbursement frameworks for digital health are evolving in the West, Asia-Pacific is behind. APAC requires an assessment framework to inform decision-making in the context of individual health systems while promoting timely, efficient, and equitable access to digital health.

APACMed proposes a value framework in its Reimbursement Position Paper[3], based on current practices in Germany, the UK, Korea and France:



Summary of Scenario-based Case Discussions

The Policy Forum included a moderated case discussion in each country based on a hypothetical digital therapeutic product ("Product X") designed to treat and manage Major Depressive Disorder (MDD).

Product X – PICOS Framework

Element	Company information
Population	Adults with confirmed diagnosis of a mild or moderate depressive episode
Intervention	Product X (Internet based intervention program in addition to care as usual)
Comparator(s)	Participants received care as usual as well as an additional digital brochure with general information on depressive disorders and services for people seeking self-help
Outcomes	**Clinical, Cost and QoL effectiveness**: • Costs of statutory health insurance • Depression severity • Health-related quality of life • Impairment in functioning
Clinical claim	• The Product X shows the potential of innovative e-mental-health programs in treating depressive disorders. The results showed that in comparison to care as usual, it leads to a significant reduction in costs of statutory health insurance with a simultaneous reduction of depressive symptoms, an increase in health-related quality of life and a decrease of impairment in functioning. • A non-interventional observational study conducted in outpatient practices also confirms the results from numerous RCTs that Product X can be used effectively and safely in the routine care of depressed outpatients.

Policymakers considered three scenarios in the context of their healthcare systems and indicated whether funding DTx was feasible given the level of clinical, economic, and other data:

Scenario 1: Unmet Need is Low/Clinical Evidence is Strong/Economic Evidence is Low and Uncertain

The perceived unmet need in Major Depressive Disorder (MDD) is relatively low. There are multiple options available that provide good patient outcomes. There are enough physicians and therapists available who provide affordable Cognitive Behavior Therapy (CBT) services to patients, which are partially subsidized. The disease burden of MDD does not rank within the top ten health priorities in the country.

The clinical evidence available is strong and includes a systematic review of randomized controlled trials demonstrating that Product X is superior to the current standard of care (SoC) as an adjunct treatment to pharmacotherapy. The safety profile is non-inferior to the SoC.

The economic evidence includes a cohort-based Markov model that supports the superiority claim with minimal uncertainties. However, there is a moderate budget impact expected from funding Product X. Politically, there is pressure to keep the healthcare budget under control. However, the committee operates independently.

Discussions on Scenario 1

The likelihood of reimbursement was discussed in depth in the closed-door session. While most of the countries had favorable opinions, the suitability of Real World Evidence (RWE) for consideration was also mentioned.

Scenario 2: Unmet Need Is High/In the Top 10 Health-Related Priority/Clinical Evidence Is Moderate (Indirect Treatment Comparison With Soc)/Economic Evidence Is Weak (Small Quality-Adjusted Life Year Gain and Unstable Incremental Cost-Effectiveness Ratios)

The perceived unmet need in MDD is high. Although multiple options are available, patient compliance and intolerance mean there is a huge unmet need. Although subsidized, there is a limited number of physicians and therapists who can provide CBT. There is a high out of pocket (OOP) cost for patients to access CBT (travel costs). The disease ranks within the top 10 health priorities, there is political pressure to do more, and patient groups are active and highly vocal.

The clinical evidence available is moderate, supported by a single-arm study using Product X in combination with a background antidepressant (AD). There is an ITC versus the current standard of care (adjunct CBT). Due to heterogeneity, there is a high degree of uncertainty in the ITC. There is a retrospective study showing that AD + CBT only works in a segment of patients. This is the basis for the superiority claim. The safety profile is claimed to be non-inferior to the SoC.

The economic evidence includes a cohort-based Markov model that supports the superiority claim with minimal uncertainties. However, there is a moderate budget impact expected from funding Product X. Politically, there is pressure to keep the healthcare budget under control. However, the committee operates independently.

Discussions on Scenario 2

In this scenario, most of the countries perceived that Product X is less likely to be reimbursed, or that it could be restricted to a low reimbursement rate or limited patient segment. The country-specific implications of low clinical evidence and other criteria were discussed at length in the closed-door session.

Scenario 3: Unmet Need is High/Clinical Evidence is Moderate/Economic Evidence is Weak (Small QALY Gain and Unstable ICER)/Coverage with Evidence Development (CED) is an Option

The perceived unmet need in MDD is high. Although multiple options are available, patient compliance and intolerance mean that there is a huge unmet need. Although subsidized, there is a limited number of physicians and therapists who can provide CBT. There is a high OOP cost for patients to access CBT (travel costs). The disease ranks within the top 10 health priorities, there is political pressure to do more, and patient groups are active and highly vocal.

The clinical evidence available is moderate, supported by a single-arm study using Product X in combination with a background AD. There is an ITC vs. the current standard of care (adjunct CBT). Due to heterogeneity, there is a high degree of uncertainty in ITC. There is a retrospective study showing that AD + CBT only works in a segment of patients. This is the basis for the superiority claim. The safety profile is claimed to be non-inferior to SoC.

The economic evidence shows that QALY gains are minimal and ICERs are unstable. However, there is an option for Coverage with Evidence Development (CED) in your country that would allow manufacturers to collect data to address key uncertainties.

Discussions on Scenario 3

This scenario was found to be the least likely to be funded across all countries, given the lack of clinical and economic evidence. Country-specific implications were discussed at length in the closed-door session.

Expert Perspectives on the Suggested Reimbursement Framework by APACMed

Across the four countries, no separate reimbursement framework for digital health has been established and, according to the experts, there is a low likelihood of establishing such a framework.

The table below summarizes the prioritization of the factors from the suggested framework taken into consideration when evaluating the hypothetical digital therapeutic product in Session 3:

Safety and clinical effect				
Economic impact				
Patient and social aspects	*	*	*	*
Organizational aspect				
Technical aspect				
Usability				
Interoperability				
Data security				
Other(s)	Alignment with national strategy, Unmet need	Alignment with national or institutional strategy	-	-

QALY: Quality-Adjusted Life Year; ICER: Incremental Cost-Effectiveness Ratios; CED: Coverage with Evidence Development

High priority | Medium priority | Low priority | Minimum requirement

*Current view does not consider patient empowerment

Role of Patient Empowerment in Overall Evidence for Reimbursement of Digital Health Technologies:

To highlight the role of patient representation in the future of digital health, the forum discussed varied examples of patient personas.

Below are extracts from the presentation by the founder of a digital health company that provides an online platform to inform patients and caregivers about chronic disease management:

Person with Obesity and High Cholesterol

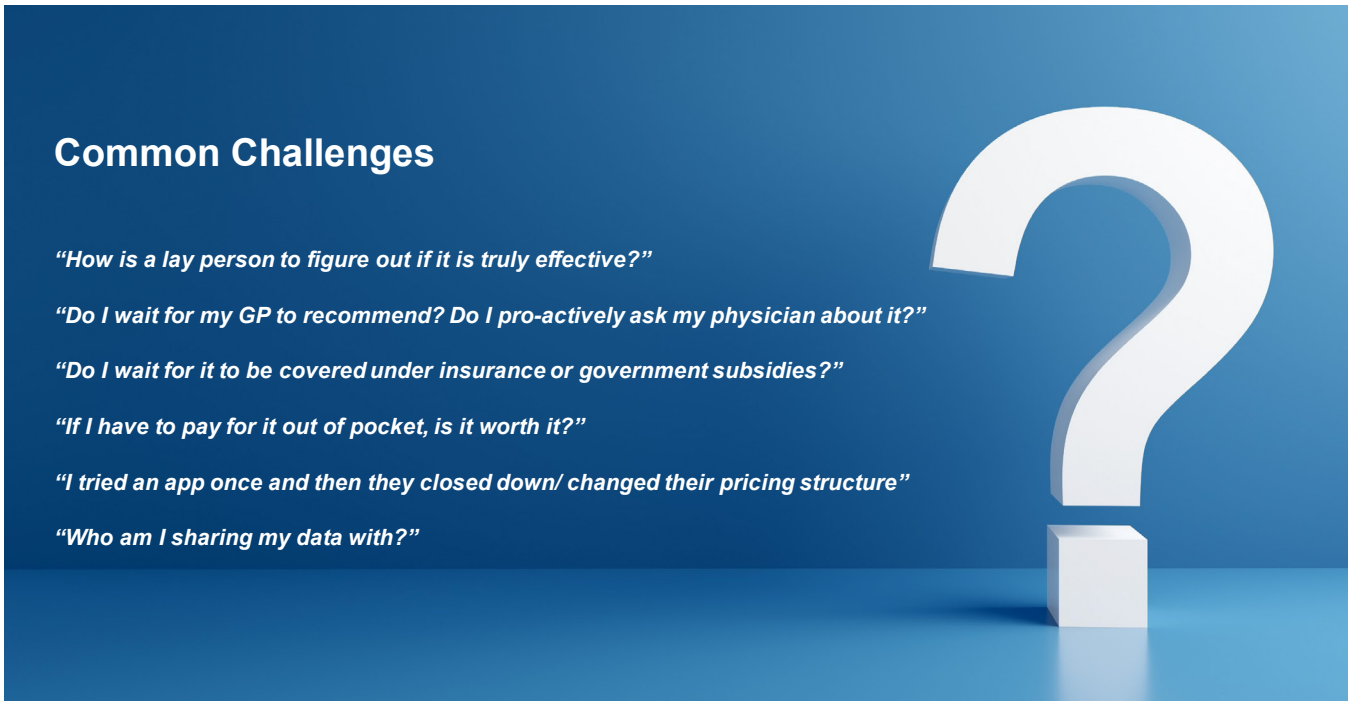
- Mr W, 42
- Issue with cholesterol and obesity
- Has tried fitness trackers, helps a little in keeping active
- Online content is very confusing in terms of diet and nutrition and exercise
- "I tried a health app for three months and saw some results. Can't keep paying on an ongoing basis. I need the ongoing coaching and support."

Person with Diabetes

- Mr. T, 65
- Managing diabetes for over 25 years
- Reasonably well controlled diabetes with medication
- Self monitoring through finger pricks – 5 to 7 times a day
- Still had periods of hypoglycemia which were troubling. Was concerned
- Discussed CGM option with treating physician
- Cost was obviously a factor. A minimum commitment of about 150-200 SGD for 14 days and a learning curve
- Delayed this for months.
- Eventually decided to get a CGM system and did a 14 days test. Found the learnings very useful to finetune the medications and diet.
- May repeat this again. Ideally would like to do this at least once in 6 months based on discussion with physician

Person after Stroke

- Mrs. A, 54
- Had a stroke 3 years ago
- Struggled to go for post stroke rehab twice a week.
  - Needed time and support of caregiver to accompany him.
  - Sometimes too depressed to go.
  - Sometimes the pain was high
  - Transport challenges
- Aware that if they could do the rehab work every day, it would improve the outcomes significantly
- Finds it very difficult to continue with the rehab exercises at home. Getting a therapist at home is expensive
- Tough for the caregiver to make time to support rehab at home. Plus it strains the relationship
- Has heard of new computer interface neuro rehab technology or gaming based neuro rehab
- Since it is fairly expensive and not covered by insurance or by government subsidies, not able to ascertain if the cost is worth it, if it is safe, reliable



Patient empowerment/patient voice is still in the early stages of development across the four countries. The unique challenges specific to each country were discussed in a closed-door session, revealing a common hurdle: the difficulty in quantifying the evidence.

At this stage, the role of the patient voice primarily centers on prioritizing technologies for funding consideration, while clinician inputs are more significant for decision-making. Patient voice is not yet integrated into the broader framework of reimbursement evaluations.

Conclusion

Despite the rapid and continuous evolution of digital health technologies, not only in the Western world but globally, there is no proven formula for success when it comes to reimbursement.

As reimbursing digital health solutions is crucial to bring more high-quality care to the market and to patients, whilst helping governments to contain costs, APACMed's Digital Health Reimbursement Alliance is committed to driving dialogue among policymakers and experts across APAC for the advancement and adoption of digital health technologies in the region.

References

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2. Reimbursement Coverage Decision Making for Digital Health Technologies in South Korea: Does It Fit the Value Framework Used in Traditional Medical Technologies?
3. APACMed Reimbursement Position Paper

For more information, visit:
http://www.apacmed.org./

Contacts:

Roberta Sarno

Digital Health Reimbursement Alliance
rsarno@apacmed.org

Amardeep Udeshi

Senior Vice President,
EVERSANA APAC
amardeep.udeshi@eversana.com