

POLICY PATHWAYS FOR VALUE ASSESSMENT AND REIMBURSEMENT OF DIGITAL HEALTH TECHNOLOGIES IN INDIA

POSITION PAPER



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Introduction

Key Takeaways:

- Globally, the penetration of telehealth (remote patient diagnosis, treatment, monitoring) has increased from 11% to 46% over the recent months.¹
- In the Asia-Pacific, some of the mainstream digital health platforms have seen a jump in usage by 150%.²
- India has experienced an increased demand for digital health solutions like teleconsultation and care at home since COVID-19. While the non-metro cities witnessed a 750% growth in online consultations from pre-COVID levels, the metro cities had an increase to the tune of 450%.³
- In order to ensure access to digital health technologies to patients at large, it is essential to have well-defined value assessment and reimbursement pathways for different types of digital health solutions.

Digital health technology is reshaping healthcare systems around the world. India has also experienced a remarkable shift in the demand for digital health solutions since COVID-19. During the pandemic, while the non-metro cities in India witnessed a 750% growth in online consultations from pre-COVID levels, the metro cities had an increase to the tune of 450%. This increase in virtual consultations, remote patient monitoring, and digital surgery using robotics, computer-assisted imaging, and artificial intelligence, calls for adapting the existing reimbursement policy frameworks for digital health.

To realize the benefits of digital health solutions and to ensure their economic sustainability and coverage, incorporating evidence-based value assessments and reimbursement best practices is important. As a first step towards achieving this paper focuses on driving value assessment and reimbursement for Digital Health in India through:

- Assessing the adoption of existing Digital Health frameworks and, highlighting the key challenges and opportunities in reimbursement pathways
- Share learnings and best practices from the APAC region on Digital Health Coverage and Reimbursement
- Recommending policy pathways and fit-for-purpose evidence generation & value assessment to ensure greater access to Digital Health solutions

Definition of Digital Health

Keeping a focused view of the paper in mind, we can leverage a definition of Digital Health from Seth Frank version, being used by many key organizations such as the World Health Organization (WHO).⁴

“First introduced in 2000 by Seth Frank two decades ago, Digital Health largely encompassed internet-focused applications and media to improve medical content, commerce, and connectivity. The term Digital Health has now expanded to encompass a much broader set of scientific concepts and technologies, including genomics, big data, artificial intelligence, 3D printing, Software as a Medical Device (SaMD), virtual and augmented reality, robotic surgery, analytics, wearables, biosensors, digital therapeutics (i.e. smart pills), mobile health, companion diagnostics, mobile applications, and telemedicine.”

Digital Health products and solutions have also been defined as medical technologies and related services which utilize information and communication technologies (ICTs) across the whole range of functions that affect the health sector, that can improve prevention, diagnosis, treatment, monitoring, prediction, prognosis and management of health and lifestyle.⁵ It may also be worthwhile to define two commonly used terms for types of digital health solutions in the form of software:

SaMD vs SiMD

According to the International Medical Device Regulators Forum (IMDRF):

Software as a Medical Device (SaMD) is a software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. For example, a mobile app to diagnose skin cancer.

Software in a Medical Device (SiMD) – is a software which is necessary for a hardware medical device to achieve its intended purpose. It is also referred to as “dependent” or “embedded” Software. For example, a software that powers the mechanics of a medical device.

Source: “Software as a Medical Device (SaMD): Key Definitions”. IMDRF: Dec 2013

At Asia-Pacific Medical Technology Association (APACMed), we are focused on the treatment of Digital Health as medical use, with bespoke needs that are beyond B2C models yet also not the same as a traditional medical device. APACMed established a Digital Health Committee in 2020. The Committee covers a wide range of Digital Health topics with bespoke sets of tools and collateral for government leaders in the Asia-Pacific. **One of the key focus area for the Digital Health Committee is to support policymakers in the establishment of optimal reimbursement schemes for digital health solutions across APAC. In view of the same for the purpose of the current paper, the focus on digital health is limited to current coverage and reimbursement landscape in India for three significant areas of Digital Health technology (a) Telemedicine, (b) Remote patient monitoring (RPM), and (c) Digital surgery technologies.**

Definition of Terminology	Example
<p>Telemedicine is defined as the use of communications technology to deliver health care to patients at a distance⁶</p>	<p>eSanjeevani- National Teleconsultation Service</p>
<p>Remote patient monitoring (RPM), or 'home telehealth,' is a subset of telemedicine that includes technology in a patient's home that records biometric data and transmits it to a central monitoring facility for interpretation⁷</p>	<p>Continuous glucose monitoring systems for diabetes management</p>
<p>Digital Surgery is defined as the use of technology for the enhancement of preoperative planning, surgical performance, therapeutic support, or training, to improve outcomes and reduce harm⁸</p>	<p>Robotic Surgery</p>



Current Digital Health Landscape in India

Key Takeaways:

- India is already on a path to digital transformation with key emphasis on digitalizing health through initiatives such as ABDM, eSanjeevani, etc. With the presence of an enabling environment for the use of digital health technology, the need of the hour is to support its access, coverage, and sustainability.
- However, the existing reimbursement processes do not capture the intrinsic differences between conventional healthcare and digital health.

India has a booming digital innovation ecosystem which is catalyzing a considerable increase in the digital health products available in the market. Some noted examples of the digital health services available in the country are preventive and self-monitoring applications, diagnostics, e-pharmacy, primary care and care-at-home, telemedicine, precision medicine, self-monitoring applications and access platforms, remote monitoring, and mobile health.

The country is already on the path of digital transformation as is evident from the following-

- **An increased focus on digitalizing health** through adoption of Ayushman Bharat Digital Mission (ABDM).
- With **increased smartphone use and digital literacy** along with higher internet penetration rates, **an enabling environment for digital health** is being created in the country.
- During the pandemic, Indian **government's flagship telemedicine technology - eSanjeevani** was instrumental in facilitating access to healthcare remotely. This is an example how Digital Health could be a game-changer for enabling access to 70% of the country's population which lives isolated in remote areas.

JOURNEY OF DIGITAL HEALTH POLICY LANDSCAPE IN INDIA⁹

The digital health space in India has gained a central place in the policy discussions since the past two decade.

With the launch of Digital India campaign in 2015, a foundation for strengthening the digital landscape in the country was created.

The National Health Policy 2017 highlighted the move towards digital tools for improving access and quality, and cost-saving.

The next big change came with the launch of NHA's flagship scheme Ayushman Bharat- Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) in 2018 which provides coverage to 100 poor families with a health insurance coverage of up to Rs. 500,000 each. This is helping to improve access to medical innovations and has potential to create an enabling environment for reimbursement of digital health technologies.

2015

2017

2018

2022

2020

2019

The Digital Personal Data Protection Bill, 2022: Ministry of Electronics and Information Technology after deliberating on various aspects of digital personal data and its protection has formulated a Draft.

The launch of Ayushman Bharat Digital Mission and Telemedicine Practice Guidelines in 2020 are the right steps towards integrating the digital health infrastructure in India

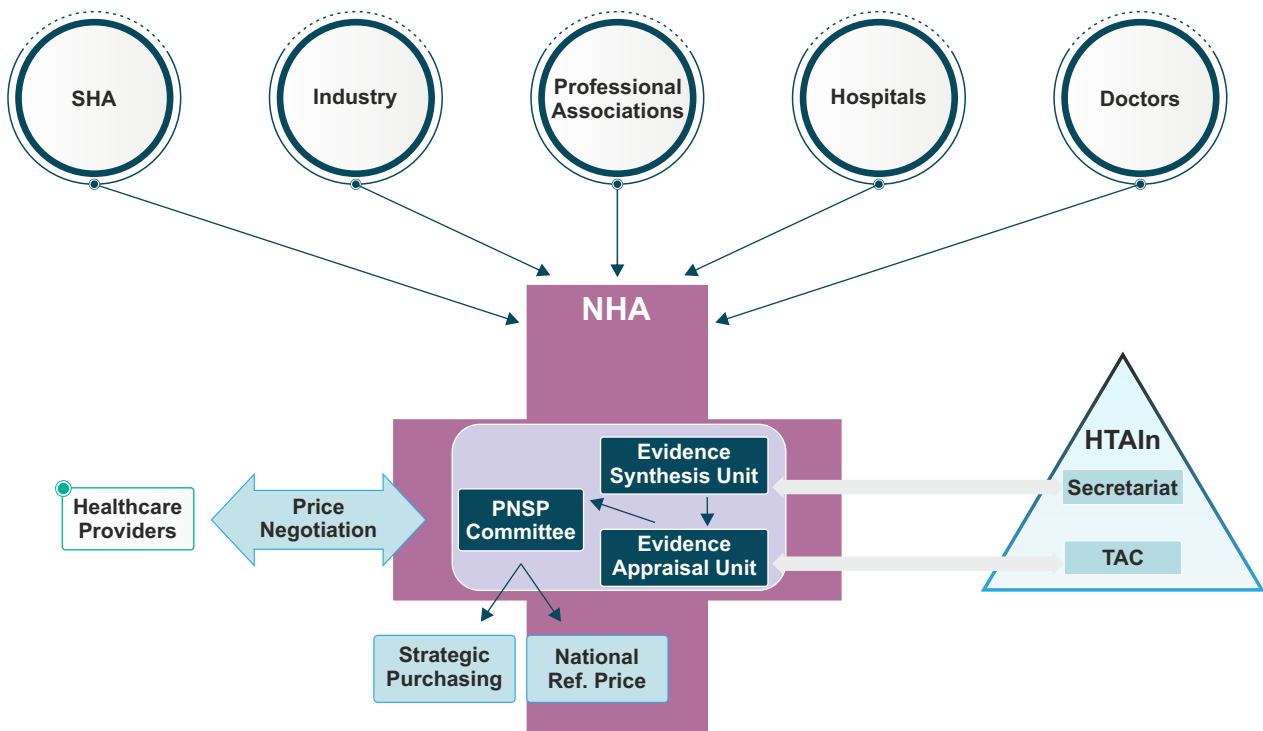
A blueprint for National Digital Health was released in 2019 forming the building blocks for the digital health mission in the country.

Current Reimbursement Landscape

The healthcare reimbursement landscape in India comprises of both Public and Private insurance, although there is no explicit standards or guidelines for digital health reimbursement in India.

Public insurance: Currently, 45% of the population in India is covered under public insurance schemes. Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY), the largest of these, is a nationwide scheme providing health insurance for secondary and tertiary care hospitalization of Rs. 5 lakhs (~\$7,000) per family annually.¹⁰

Figure 1: Structure and function of the newly instituted HeFTA unit under National Health Authority (NHA)¹¹



Source: Consultation paper on Provider Payments and Price Setting under AB-PMJAY Scheme in India

The process for inclusion of new technologies in the PMJAY starts with the requests for inclusion by the user department. All the topics received by the National Health Authority (NHA) undergo a topic prioritization stage based on some pre-established criteria. The newly instituted Health Financing and Technology Assessment (HeFTA) unit will use Health Technology Assessment (HTA) evidence to inform decisions regarding inclusion and non-inclusion of interventions and procedures in the Health Benefits Package (HBP). Decisions regarding the costing and pricing of newer technologies proposed for inclusion in the HBP will also be under the purview of this unit. Within the HeFTA unit, there will be three sections with different roles as shown in the figure X- Evidence synthesis unit, Evidence appraisal unit and Price Negotiation and Strategic Purchasing committee.

Private Insurance

India's private health insurance landscape comprises of over 30 private insurers.¹² There has been a considerable rise in the demand for private health insurance since the pandemic. Among digital health interventions, IRDAI has mandated telemedicine to be covered under private health insurance.¹³ But since most of the private insurers do not consider outpatient consultation under their standard insurance cover, wider coverage for telemedicine has still not been realized. During

COVID-19, several insurance companies introduced new policies to include home based care through telehealth, marking a shift in the traditional approach towards telemedicine. With the growing demand for telemedicine, many employers are also covering access to subscription-based telehealth services for their employees through a partner organization. Under the 'Guideline of the Standard Individual Health Insurance Product' IRDAI has included robotic surgeries as an in-patient in a hospital upto 50% of sum insured specified in the policy schedule.¹⁴

Challenges for digital health reimbursement in India

01

The **regulatory landscape governing digital health in the country is not clearly defined** with a long road to achieving a robust digital ecosystem. The detailed regulatory challenges can be referred to in another APACMed driven published position paper titled 'Digital Health regulation in India- Overview and best practices.'¹⁵

02

There is a **lack of consistent set of definitions and categorizations** for Digital Health within the current reimbursement evaluation. Due to an absence of specific value assessment for Digital Health, general HTAs are often deployed following the same principles despite inherent differences in the technologies.

03

Limited availability of long-term clinical data and economic impact of DHT could potentially be a deterrent for establishing value and therefore funding related decisions by payers.

04

Reimbursement policy designs have certain **limitations including coverage of only inpatient and episodic hospitalizations, absence of co-pay, and considering device cost as the primary evaluation criteria, etc.** Additionally, health being a state subject further acts as a major barrier to adopting the digital health solutions in a unified manner.

05

Limited knowledge/ familiarity amongst healthcare stakeholders towards rapidly and constantly evolving digital health solutions

Learning from Other Countries in the Region

In the APAC region, reimbursement and HTA guidelines for Digital Health are limited, and Digital Health solutions are often regulated as medical devices. Current reimbursement policies in Australia, Japan, South Korea and Thailand are summarized in **Table below**. Reimbursement policies in these countries currently cover Telemedicine, Remote monitoring, AI, 3D printing, SaMD and Robotic surgery. Telemedicine is the most often reimbursed technology, being covered by national health insurers in Australia, China, Japan, Korea, Taiwan and by private in Singapore and Vietnam. Remote monitoring is the second most reimbursed technology, with dedicated frameworks in Australia, Korea, and Japan. Smart infusion pumps, used for purposes ranging from diabetes to cancer are reimbursed in Korea, China, and Thailand. Robotic surgery and teleradiology are reimbursed in South Korea.¹⁶

Digital Health Landscape in the Region

Australia:

- *Though there is a lack of dedicated value assessment frameworks for digital health, Australia's National Digital Health Strategy intends to formulate the future policies for Digital health reimbursement*
- *Digital Health technologies have been increasingly covered including Telehealth, Remote monitoring, and Continuous Glucose Monitoring.*

Japan:

- *Currently, DHTs do not have a specific assessment framework, they are evaluated alongside medical devices*
- *Some reimbursement for remote monitoring, exams, robotic surgery and CGM is provided by Japan*

South Korea:

- *South Korea is the only country in APAC which has developed a value assessment guideline for DHTs, namely AI and 3D printing technology.*
- *In October 2022, there have been revisions to country's "Assessment Guideline for National Health Insurance Coverage Eligibility of Innovative Medical Technology". These revisions introduce positive changes to the guidelines for "AI-embedded medical technology (radiology field and pathology field) and medical technology using 3D printing"*
- *Digital health technologies like Smart infusion pumps, Robotic surgery and teleradiology are reimbursed in South Korea*

China:

- *The Chinese government has supported the use of DHTs extensively though there is a lack of a comprehensive reimbursement model for DHTs is its biggest drawback.*
- *Technologies like Telemedicine and Smart pumps are currently reimbursed in the country*

¹⁶ <https://apacmed.org/content/uploads/2022/03/Masterdeck-Skill-up-with-APACMed-How-to-get-digital-health-reimbursed-in-Korea.pdf>

Approaches to Manage, Evaluate & Reimburse Digital Health Technologies

Health System Layer	Driving Entity	Reimbursement Approach
Multilateral	• HIMSS	• Interoperability criteria for monitoring personal health, wellness
	• FDA	• Various including evaluation framework for medical software and mobile apps
	• WHO	• Product lifecycle evaluation and validation general framework
	• European Commission	• Standalone software qualification and classification
	• IMDRF	• SaMD definition, risk categorization framework, clinical evaluation
	• UK NHS	• NICE evidence standards framework and code of conduct
Geography	• Australia	• Telehealth, remote monitoring, Continuous glucose monitors (CGM) services increasingly covered
	• China	• Guizhou Province pilot program for telemedicine reimbursement
	• Japan	• Some reimbursement of remote monitoring, exams, CGM
	• Korea	• Partial reimbursement CGM, likely leading to full coverage
Intervention	• HeartFlow Analysis	• Reimbursement in Japan (AI imaging for cardiology)
	• Da Vinci Robot	• Reimbursement in Japan, Korea (robotic surgery)
	• FreeStyle Libre	• Reimbursement in Japan, Korea, Australia (glucose monitoring)
	• Space Pump	• Reimbursement in Korea, Thailand, China (smart treatment)
	• VNS Therapy	• Reimbursement in Japan, Australia, Taiwan, Korea (neuromodulation)

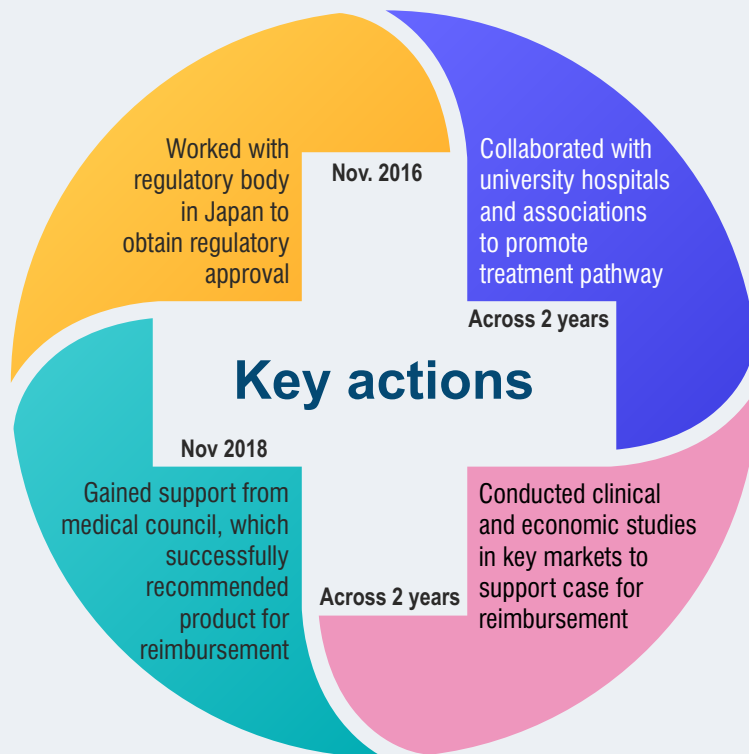
Snapshot – Heartflow Reimbursement in Japan¹⁷

Success story of HeartFlow reimbursement in Japan epitomized the DH reimbursement using a multistep approach and adoption of best practices.

A closed collaboration with key stakeholders and clinical institutions promoted the treatment pathway. Then an inception of positive environment due to market shaping and promotional efforts integrated with better value assessment supported the case for reimbursement of HeartFlow (please refer to Figure 2)

Figure 2: HeartFlow Successfully gained reimbursement in Japan using a multistep approach and adoption of best practices

Heart Flow multistep approach in adopting best practices



Source: Corporate Website, news articles, L.E.K. analysis

Key Recommendations

Digital Health provides a transcendent opportunity much needed to drive and transform Indian healthcare onto a sustainable path while improving patient outcomes effectively.

The Indian health system is currently in a phase of transition towards Universal Health Coverage. Digital health reimbursement therefore becomes crucial for access and timely adoption of advanced treatments through digital health solutions in a more equitable manner. Digital health technologies would be instrumental in improving the efficiency of all Government health missions by strengthening healthcare delivery at the individual, primary, secondary and tertiary healthcare levels.

India has demonstrated regulatory agility through global cooperation during the COVID-19 pandemic and utilized Digital Health solutions immensely by maintaining rigorous standards for assessing safety and efficacy. Such approaches should be applied for digital health regulations in future by creating an ecosystem that encourages digital health innovation as well as their reimbursement.

A clearly defined transparent framework with specific reimbursement criteria to assess the value of DHT for inclusion into health benefit packages (HBPs) under AB-PMJAY is required at a central level. Advocacy for better value assessment will create a positive policy environment for digital technologies and will open the door for increased access to Digital Health solutions going forward.

Key Recommendations



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Annexure 1

Few Examples of Existing DHT Tools & Technologies in India and their Reimbursement Status

S. No.	Name of Digital tool and technology	Area of DHT	Usage	Current Reimbursement Status in India (Yes/No)	Short description about the tool/technology
1	FreeStyle Libre (Reader + Sensor) - Consumer Version (with option of remote monitoring)	Remote Patient Monitoring	Continuous Glucose Monitoring for people living with diabetes	No	FreeStyle Libre is a Continuous Glucose Monitoring system that comes with a reader and a sensor. The sensor is applied on to the back of the upper arm and can be worn for up to 14 days. Simply swipe the reader over the sensor to get a complete picture of your glucose levels. Simply swipe Reader/Mobile over the sensor to get a complete picture and share the same with HCP/Caregiver in real time.
2	FreeStyle Libre Pro (Reader + Sensor) - Professional version for Health Care Professionals (HCPs) (with option of remote monitoring)	Remote Patient Monitoring	Continuous Glucose Monitoring for people living with diabetes	No	FreeStyle Libre Pro is an innovative sensor-based 'Continuous Glucose Monitoring' device that captures glucose readings every 15 minutes for up to 14 days, and gives complete glucose profile report in the form of 'Ambulatory Glucose Profile'. Simply swipe Reader/Mobile over the sensor to get a complete picture and share the same with HCP/Caregiver in real time.
3	Remote Monitoring Bedside Monitoring Merline@home	Remote Patient Monitoring	Designed to streamline your workflow and support informed clinical decisions, the Merlin@home	No	The Merlin@home transmitter allows efficient remote care management of patients with implanted cardiac devices through scheduled transmissions and daily alert monitoring. It can

S. No.	Name of Digital tool and technology	Area of DHT	Usage	Current Reimbursement Status in India (Yes/No)	Short description about the tool/technology
			transmitter works with the Merlin.net™ Patient Care Network (PCN) for easy and efficient remote care patient management.		complement or replace in-clinic visits with remote patient transmissions.
4	Azure - Bluetooth enabled pacemaker	Remote Patient Monitoring	Pacing for Bradycardia patients	No	Azure™ is enabled with BlueSync™ technology, allowing for tablet-based programming and app-based remote monitoring.
5	Pacemaker with remote monitoring	Remote Patient Monitoring	Pacing for Bradycardia patients	No	Remote monitoring will allow patients to get their pacemakers to be checked anywhere, anytime.
6	780G System with BLE and remote monitoring	Remote Patient Monitoring	Insulin delivery with continuous glucose monitoring	No	780G is an advanced hybrid closed loop system for insulin delivery for type 1 diabetes patients above the age of 7. It has a remote monitoring feature for care partners
7	Guardian Connect (with remote monitoring)	Remote Patient Monitoring	Continuous glucose monitoring	No	Guardian Connect is a real-time standalone glucose monitoring system for use by a patient with Diabetes. It has a remote monitoring feature for care partners
8	GI Genius	Telemedicine	Detection of Polyps in colorectal cancer	No	The GI Genius™ intelligent endoscopy module is computer-aided polyp detection system powered by AI which empowers physicians to detect colorectal polyps through enhanced visualization during colonoscopy and act as second observer
9	Pillcam	Telemedicine	Monitoring lesions that may be related to Crohn's disease, obscure bleeding, or iron deficiency anemia.	No	An ingestible capsule device equipped with a miniature video camera to visualize small intestine. It is equipped with a light source, batteries, a radio transmitter, and antenna. After being swallowed, PillCam transmits >50,000 images in 8-hour period to a DataRecorder fixed to a belt worn around the

S. No.	Name of Digital tool and technology	Area of DHT	Usage	Current Reimbursement Status in India (Yes/No)	Short description about the tool/technology
					patient's waist. The small bowel images are then downloaded into a RAPID® workstation computer where a physician can view the images on video monitors and make a diagnosis.
10	Visible Patient	Digital Surgery technologies	Oncology	No	3D visualization and simulation from scans
11	C-SATS	Digital Surgical Skills Enhancement Platform	Across all specialties other than orthopedics	No	Self-learning tool for surgeons where they can upload surgery videos and assess own skills - not connected to any medical device or used in functioning of any device
12	Ablation Confirmation Software	Digital-surgery technologies	Oncology - microwave ablation	No	Used to provide information to user while using Neuwave (microwave ablation system) - user may choose to use these inputs for decision making during procedure
13	Wearable Device	Telemedicine services/ Remote patient monitoring (RPM)	Diagnosing Sleep Apnea	No	A Simple, Accurate and Safe way to assess sleep quality and diagnose sleep apnea
14	Cloud Connected	Telemedicine services/ Remote patient monitoring (RPM)	Sleep Apnea	No	Remote monitoring and clinical support has direct influence on therapy compliance. ResMed's cloud-based system for managing patients with sleep and respiratory disorders captures patient therapy data. Having remote access to patients, therapy information helps HCPs gives additional support to the patients for handholding and getting used to therapy; and allows them to address issues and problems early. This may reduce patient drop-outs and accelerate the adoption of therapy during the trial period.

S. No.	Name of Digital tool and technology	Area of DHT	Usage	Current Reimbursement Status in India (Yes/No)	Short description about the tool/technology
15	Health App	Telemedicine services/ Remote patient monitoring (RPM)	Sleep Apnea	No	Cloud-based system that manages patients with sleep-disordered breathing and respiratory insufficiency. It enables HCPs to quickly access patient data, share clinical insights with other health professionals and reduce costs related to patient follow-up.
16	Vengage	Remote patient monitoring (RPM)	Angioplasty, Congestive Heart Failure	No	This is a whatsapp based AI tool that engages patients post hospital discharge. In angioplasty, it will ensure higher adherence to medicines and improved outcomes and in CHF, it will ensure early warning signs and reduction in re-hospitalization.

Source: Basis inputs from APACMed Members



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About The Asia Pacific Medical Technology Association (APACMed)

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific, representing both multinational corporations as well as small and medium enterprises, together with several local industry associations across the region. Headquartered in Singapore and with an active presence in India, APACMed's mission is patient-centric, and we strive to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.

We are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

APACMed Corporate Members



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