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How to Navigate the Digital Health Landscape: Global Value Frameworks and Payment Pathways

Workshop #148

Monday, May 6, 2024
5:00 – 6:00 PM
Georgia World Congress Center

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WELCOME

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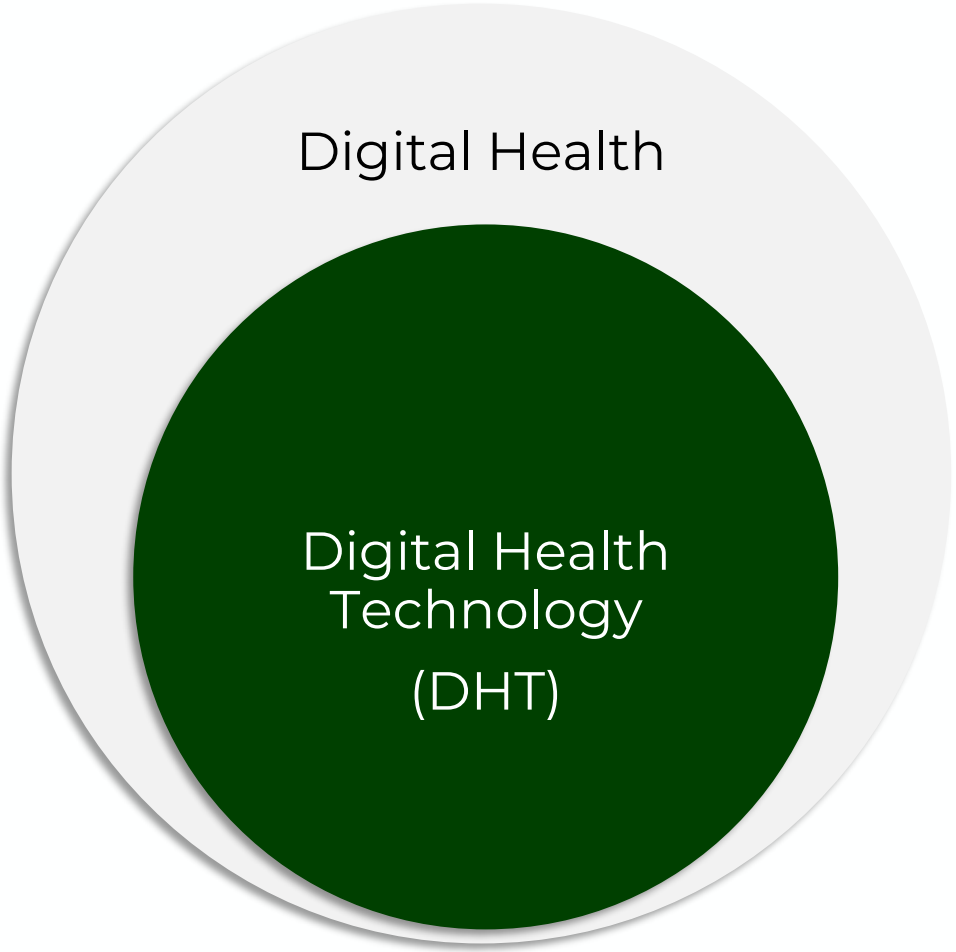
What is Digital Health? Current Definitions

World Health Organization

Digital Health encompasses:

1. Use of information and communication technologies for health
2. Use of advanced computing sciences in 'big data', genomics and artificial intelligence, telemedicine, etc.



FDA

Digital Health technologies (DHTs) are computing platforms, connectivity, software, and sensors [used] for health and related uses

NIHR | National Institute for Health Research

DHTs aim to boost our health and wellbeing, or to improve health systems

References: WHO 2023; FDA 2024; NIHR 2022

Abbreviations: WHO, world health organization; FDA, food and drug administration; NIHR, national institute for health and care research

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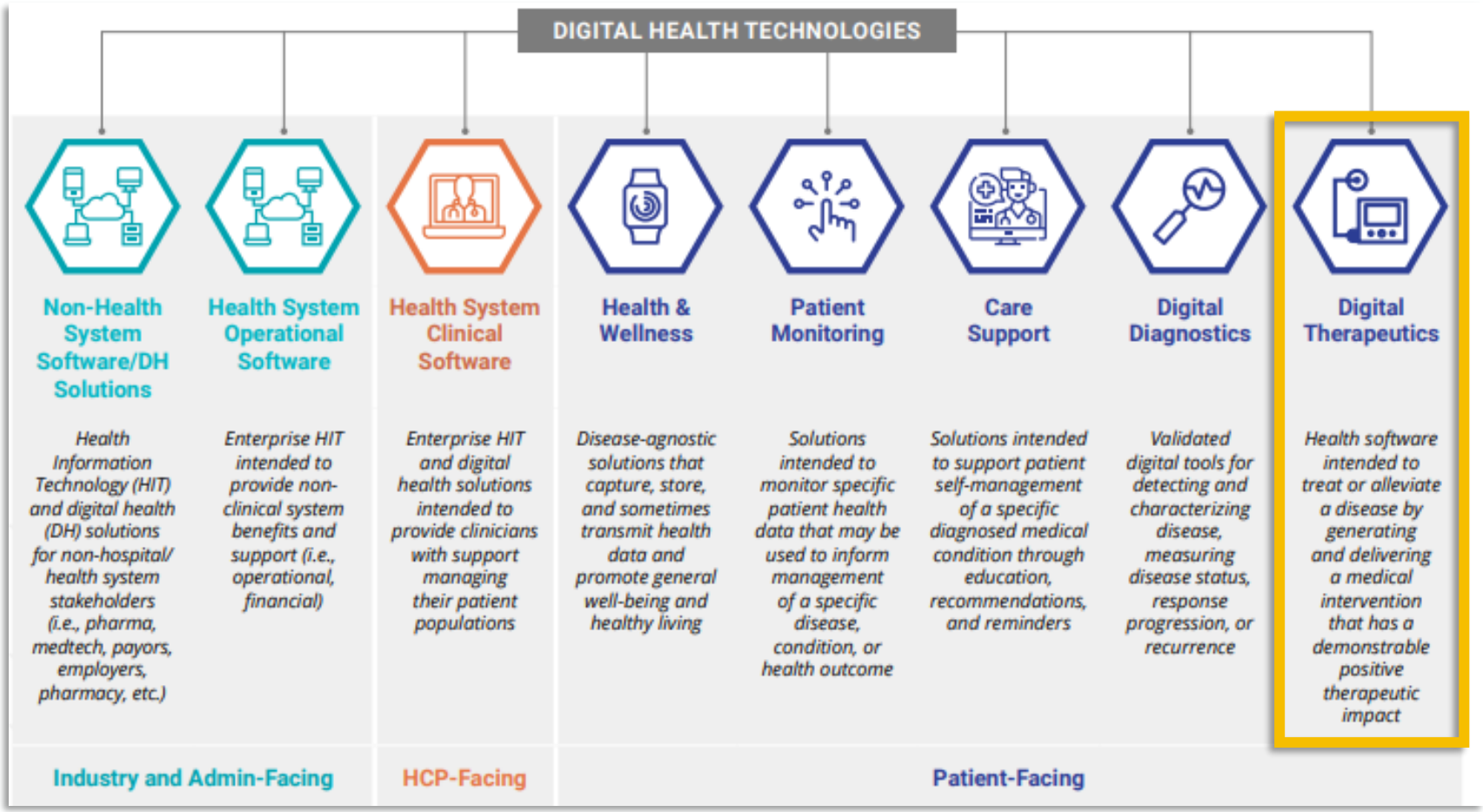
Snapshot of Evolving DHT Landscape

DHTs face increasing clinical and regulatory scrutiny, evidence requirements based on intended use and risk



* Categorizations of the DHT ecosystem will continue to evolve.

Current representation of DTx in Broader DHT Landscape

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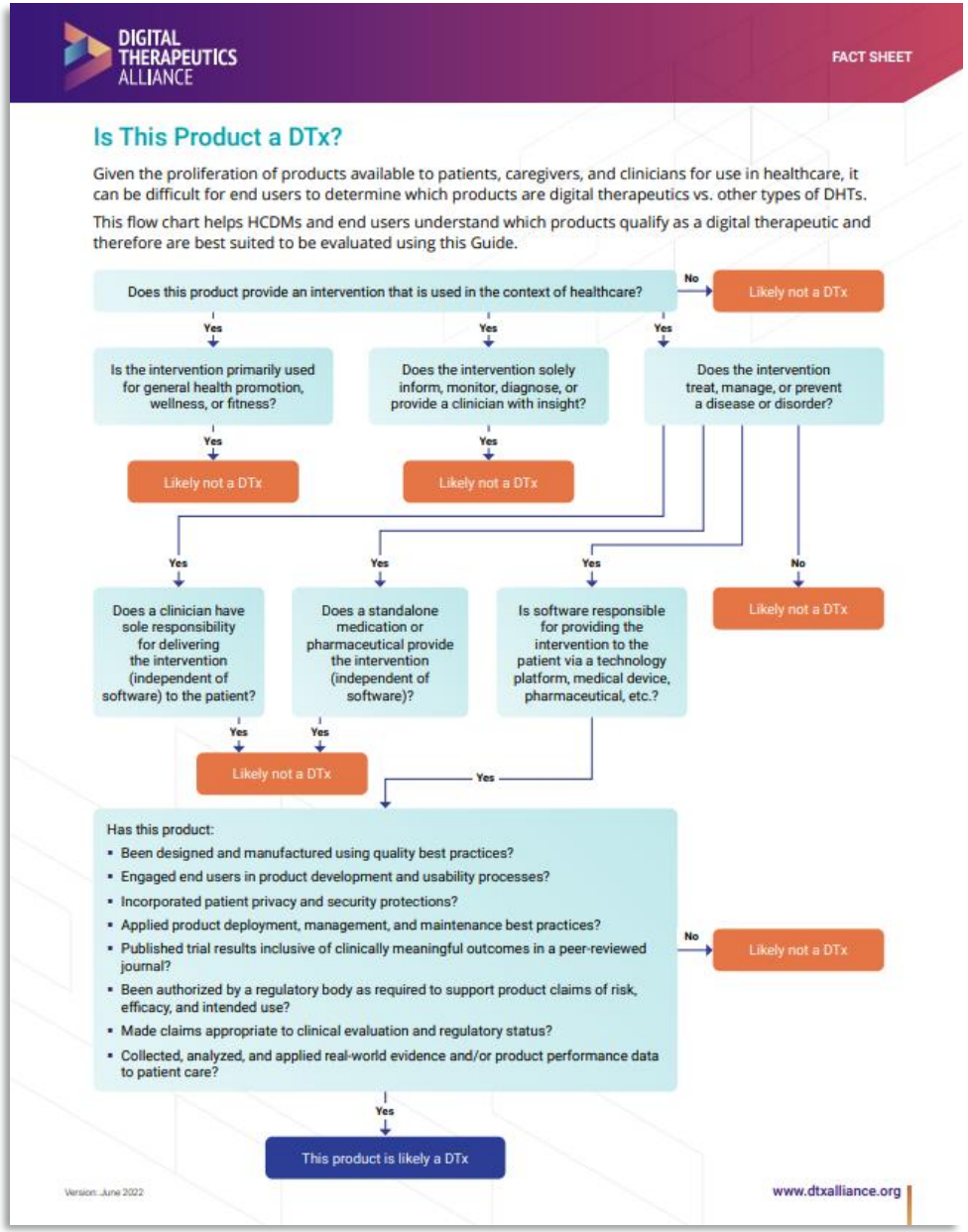
Is the product a DTx?

Recognized as ***medical devices*** subject to international, national and local standards and regulations

DIGITAL THERAPEUTICS (DTx)

1	**Deliver an intervention** directly to the patient via software
2	Evidence-based and **clinically validated**
3	Makes a **medical claim** to **treat, manage, or prevent** disease or disorder



References: Digital Health Alliance 2022

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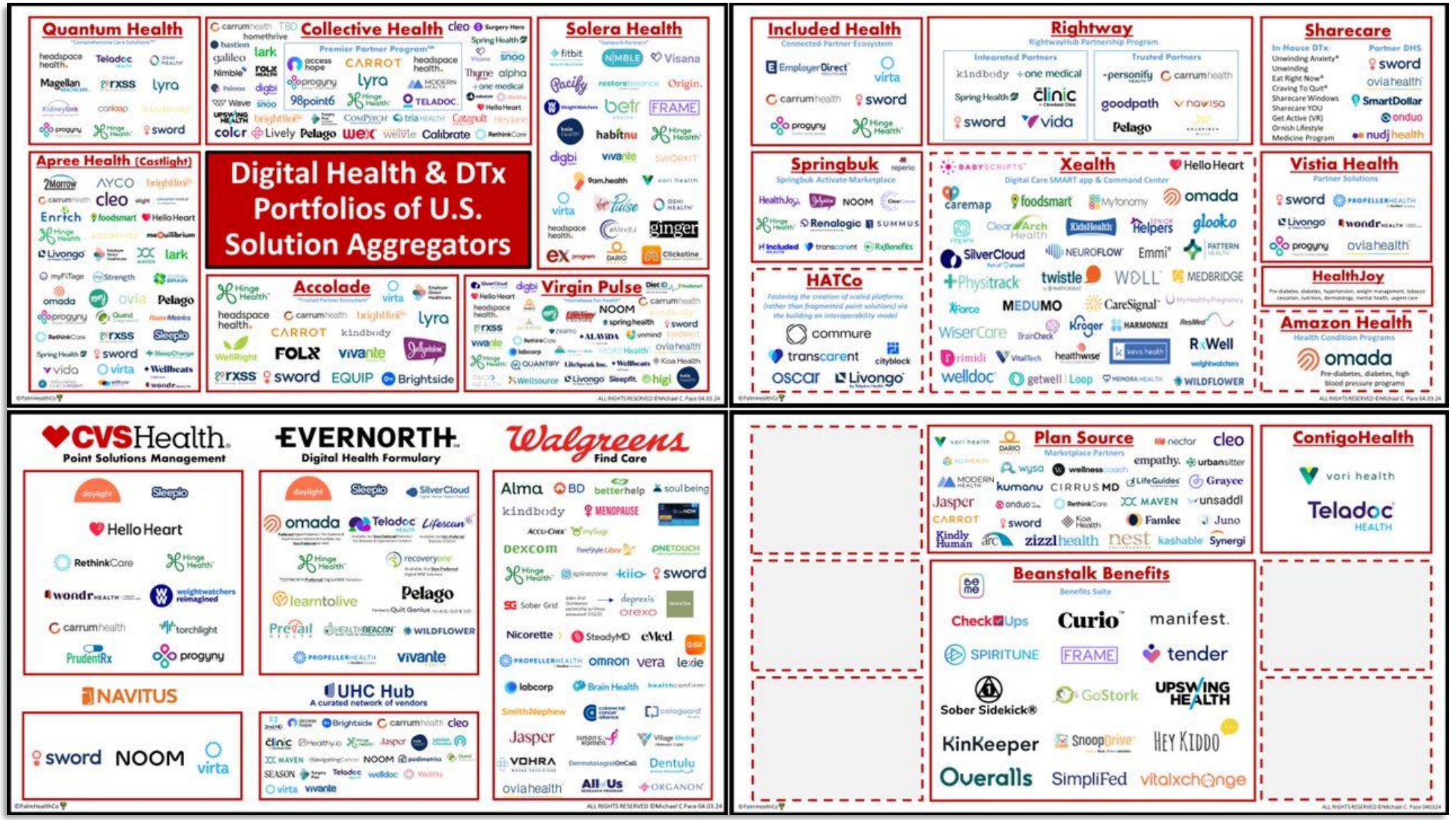
Digital Landscape in Germany

	1 Digital Prevention Solutions	2 Digital Health Applications (DiGA)	3 Digital Care Applications (DiPA)
	Before diagnosis	*For or after diagnosis*	*In care setting*
			Digital care application process finalized - first solutions expected > Q1 2023
Target group	An **insured** person (statutory health insurances)	A **patient** or **patient** and **physician** / psychotherapist **together**	A **patient** and / or **care-givers** and **nurses**
Number of solutions	Currently **19 companies** with digital prevention solutions (3 with multiple focus areas / courses)	Currently 55 **DiGAs listed**	-
Focus areas	Improvement in **stress mgmt, addictive substance consumption, fitness / exercises, nutrition**	**Recognition, monitoring, treatment or alleviation** of diseases, injuries or disabilities depending on diagnosis	**Stabilization / improvement of state of health** via exercises or improvement in **collaboration with care-givers and nurses**
Min. User Value / Reimbursement	Current range between **49-139€** for **6-14 weeks** programs (covered 80-100% by insurance)	Current average of **~450€/225€ for a 3 month** prescription (covered 100% by insurance)	Capped at **50€ per months** per patient (covered 100% by insurance)
Certified via	**Central Certification Body for Prevention** (Zentrale Prüfstelle Prävention)	**Federal Institute for Drugs and Medical Devices** (Bundesinstitut für Arzneimittel und Medizinprodukte)	
Digital since	Open for digital solutions **since July 2021**	**First DiGA** listed in **September 2020**	**First DiPAs** in **2023**

US Digital Health Formularies



2023 RPM CPT Codes

Code	Description	Fac Fee	Non-Fac Fee
99453	Initial patient set up and education on use of equipment, can be done remotely by practice staff. (Bill only once per patient, per provider, per 30-days, and only when at least 16 days of data have been collected on at least one medical device. For CGM, use codes 95250, 95249, and 95251.)	NA	19.19
99454	Delivery of results/reports by practice staff to the physician caring for the patient; can be billed once every 30 days. (Bill only once per patient, per provider, per 30-days, and only when at least 16 days of data have been collected on at least one medical device. For CGM, use codes 95250, 95249, and 95251.)	69.00	63.16
99457	First 20 minutes of physician's interpretation and interactive communication with the patient/care giver every month. "Interactive communication" involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission. (The 20 minutes includes both synchronous, real-time interactions as well as non-face-to-face care management services.)	31.75	50.94
99458	Subsequent 20 minutes of physician's interpretation and interactive communication with the patient/caregiver every month. (The 20 minutes includes both synchronous, real-time interactions as well as non-face-to-face care management services.)	31.75	41.17
99473	Specific to self-measured blood pressure monitoring (SMBP), use this code for patient education/training and device calibration. This code can only be submitted once per device.	NA	11.52
99474	Specific to SMBP monitoring, submit this code once a month for ongoing treatment decisions based on the average of the patient's SMBP readings. This code can be used when patients and/or caregivers report their BP readings back to the practice—whether it is done electronically or in person with a SMBP recording log—which then allow the physician to make ongoing treatment decisions. If 99474 services are provided on the same day the patient presents for an evaluation and management (E/M) service to the same provider, these services should be considered part of the E/M service and not reported separately.	8.72	15.00
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, requiring a minimum of 30 minutes of time, each 30 days. This code does not require interactive communication like 99457 to bill. However, it requires a physician or other QHP to perform these services and requires 30 minutes of time every 30 days (not every calendar month) to bill. 99457 and 99091 cannot be billed concurrently.	56.88	56.88
95250	Ambulatory CGM interstitial via subcutaneous sensor for a minimum 72 hrs, office provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording. (Do not report more than once a month; do not report in conjunction with 99091, 0446T)	NA	157.37
95249	Ambulatory CGM … patient provided equipment … (Do not report more than once for the duration that the patient owns the data receiver; do not report in conjunction with 99091, 0446T)	NA	58.62
95251	Analysis, interpretation, and report (Do not report more than once a month; do not report in conjunction with 99091)	35.59	35.59

American College of Physicians: https://www.acponline.org/practice-resources/business-resources/telehealth-guidance-and-resources/remote-patient-monitoring-billing-coding-and-regulations-information

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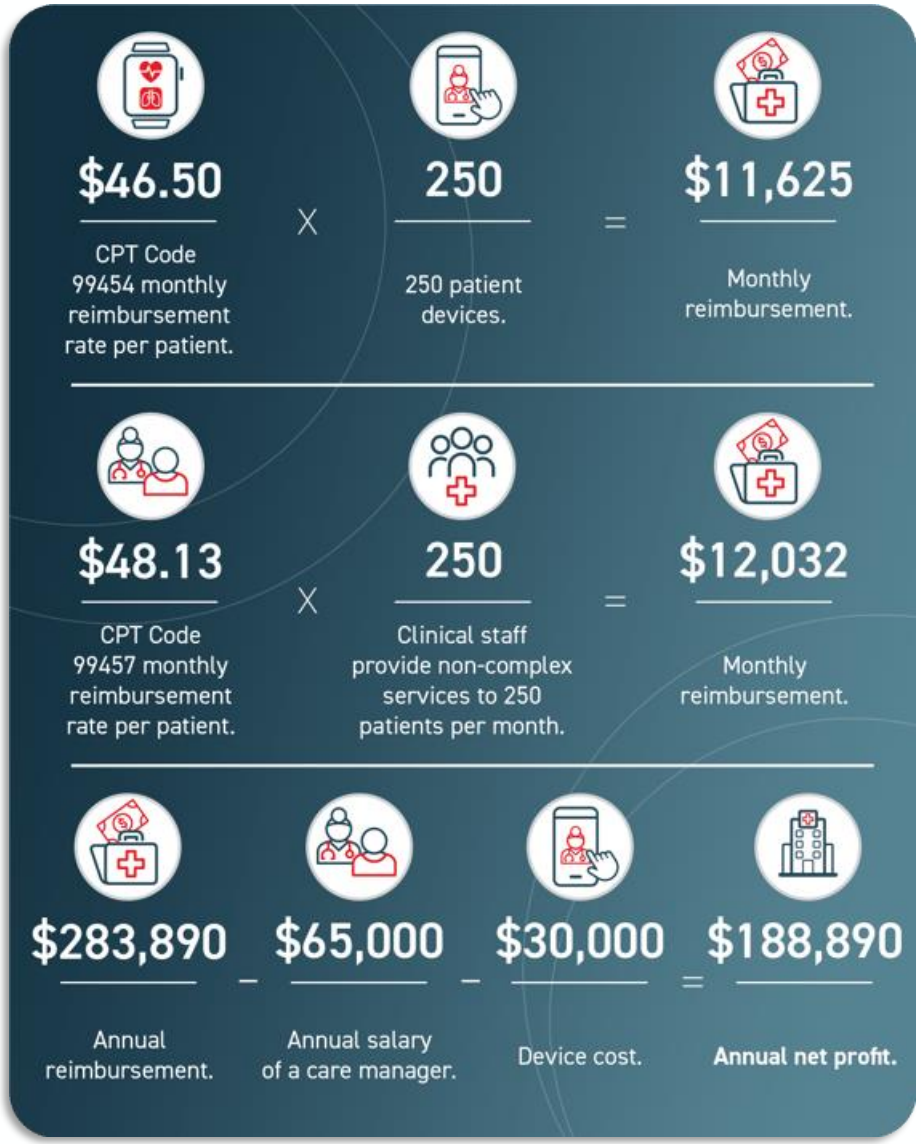
RPM provider economics can be favorable



ThoroughCare: Implementing Value-Based Care With Remote Patient Monitoring (RPM) (thoroughcare.net)

Tarantini R. 2023. Medical Economics: https://www.medicaleconomics.com/view/remote-patient-monitoring-a-win-for-both-providers-and-patients

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Case Study: Implantable Cardiac Defibrillators (ICD)

HYPOTHESIS

Alert-driven remote patient monitoring (RPM) may reduce clinic workload and promote more efficient resource allocation

METHODS

Post-implant ICD follow-up strategies assessed:

1. In-person evaluation (IPE) only
2. RPM–conventional (hybrid of IPE and RPM)
3. RPM–alert (alert-based ICD follow-up)

Method:	Cost-consequence analysis
Time Horizon:	2 years time
Perspective:	US Medicare payer
Data Source:	TRUST Study (n=1339)

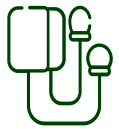
RESULTS

Mean cumulative follow-up costs per patient:

- $12,688 in the IPE group
- $12,001 in the RPM–conventional group
- $11,011 in the RPM–alert group

CONCLUSIONS

- Alert-driven RPM was economically attractive
- In scenarios with comparable patient outcomes and safety to conventional RPM, alert-driven RPM may be the preferred strategy for ICD follow-up



~800,000 people have ICDs

~ 150,000 ICDs are implanted annually

Varma N. 2007, Am Heart J. Rationale and design of a prospective study of the efficacy of a remote monitoring system used in implantable cardioverter defibrillator follow-up: the Lumos-T Reduces Routine Office Device Follow-Up Study (TRUST) study

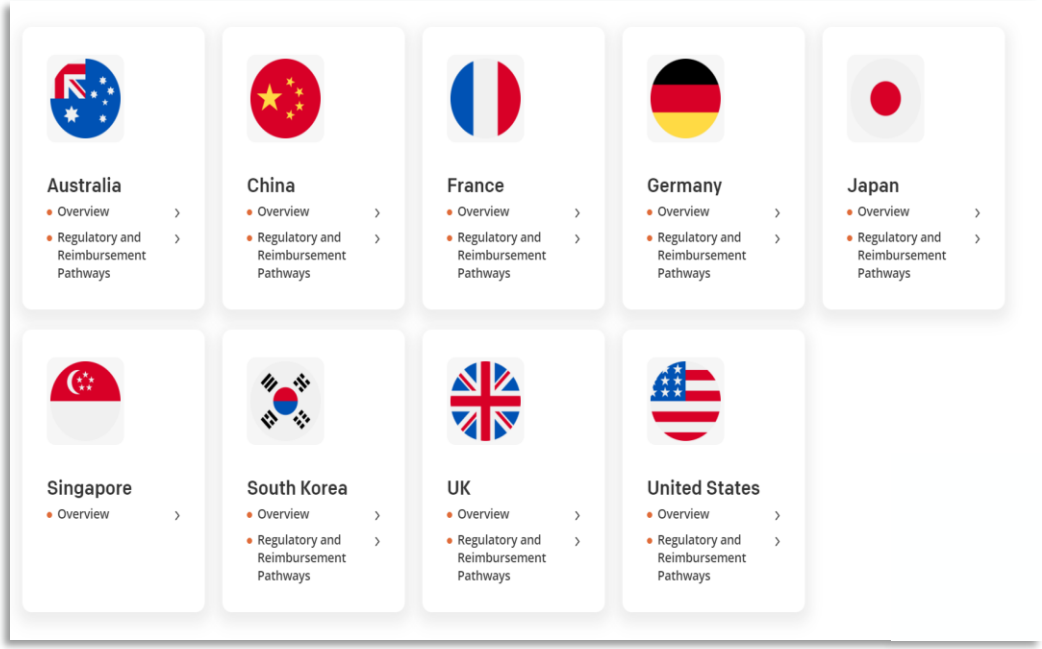
Varma N. *et al. 2021. JACC Clin Electrophysiol.* TRUST Investigators. Alert-Based ICD follow-up: a model of digitally driven remote patient monitoring

Chew D. et al. 2023, Heart Rhythm. Alert-driven vs scheduled remote monitoring of implantable cardiac defibrillators: A cost-consequence analysis from the TRUST Trial

Wrap Up: Online Digital Market Access Resources

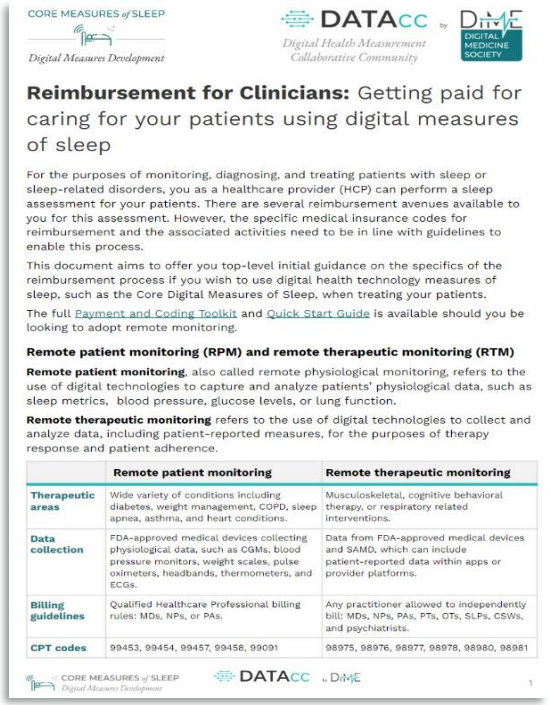
DIGITAL THERAPEUTICS ALLIANCE

DIGITAL THERAPEUTICS (DTx) BY COUNTRY



DIGITAL MEDICINE SOCIETY

DIGITAL HEALTH BRIEFS



CORE MEASURES of SLEEP — Digital Measures Development

DATACC by DiMe — Digital Health Measurement Collaborative Community

Reimbursement for Clinicians: Getting paid for caring for your patients using digital measures of sleep

For the purposes of monitoring, diagnosing, and treating patients with sleep or sleep-related disorders, you as a healthcare provider (HCP) can perform a sleep assessment for your patients. There are several reimbursement avenues available to you for this assessment. However, the specific medical insurance codes for reimbursement and the associated activities need to be in line with guidelines to enable this process.

This document aims to offer you top-level initial guidance on the specifics of the reimbursement process if you wish to use digital health technology measures of sleep, such as the Core Digital Measures of Sleep, when treating your patients.

The full Payment and Coding Toolkit and Quick Start Guide is available should you be looking to adopt remote monitoring.

Remote patient monitoring (RPM) and remote therapeutic monitoring (RTM)

Remote patient monitoring, also called remote physiological monitoring, refers to the use of digital technologies to capture and analyze patients' physiological data, such as sleep metrics, blood pressure, glucose levels, or lung function.

Remote therapeutic monitoring refers to the use of digital technologies to collect and analyze data, including patient-reported measures, for the purposes of therapy response and patient adherence.

	Remote patient monitoring	Remote therapeutic monitoring
Therapeutic areas	Wide variety of conditions including diabetes, weight management, COPD, sleep apnea, asthma, and heart conditions.	Musculoskeletal, cognitive behavioral therapy, or respiratory related interventions.
Data collection	FDA-approved medical devices collecting physiological data, such as CGMs, blood pressure monitors, weight scales, pulse oximeters, headbands, thermometers, and ECGs.	Data from FDA-approved medical devices and SAMD, which can include patient-reported data within apps or provider platforms.
Billing guidelines	Qualified Healthcare Professional billing rules: MDs, NPs, or PAs.	Any practitioner allowed to independently bill: MDs, NPs, PAs, PTs, OTs, SLPs, CSWs, and psychiatrists.
CPT codes	99453, 99454, 99457, 99458, 99091	98975, 98976, 98977, 98978, 98980, 98981

CORE MEASURES of SLEEP Digital Measures Development — DATACC — DiMe

Federal Institute for Drugs and Medical Devices

DiGA GUIDE

Bundesinstitut für Arzneimittel und Medizinprodukte

Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB V

Ein Leitfaden für Hersteller, Leistungserbringer und Anwender

Version 3.5 vom 28.12.2023

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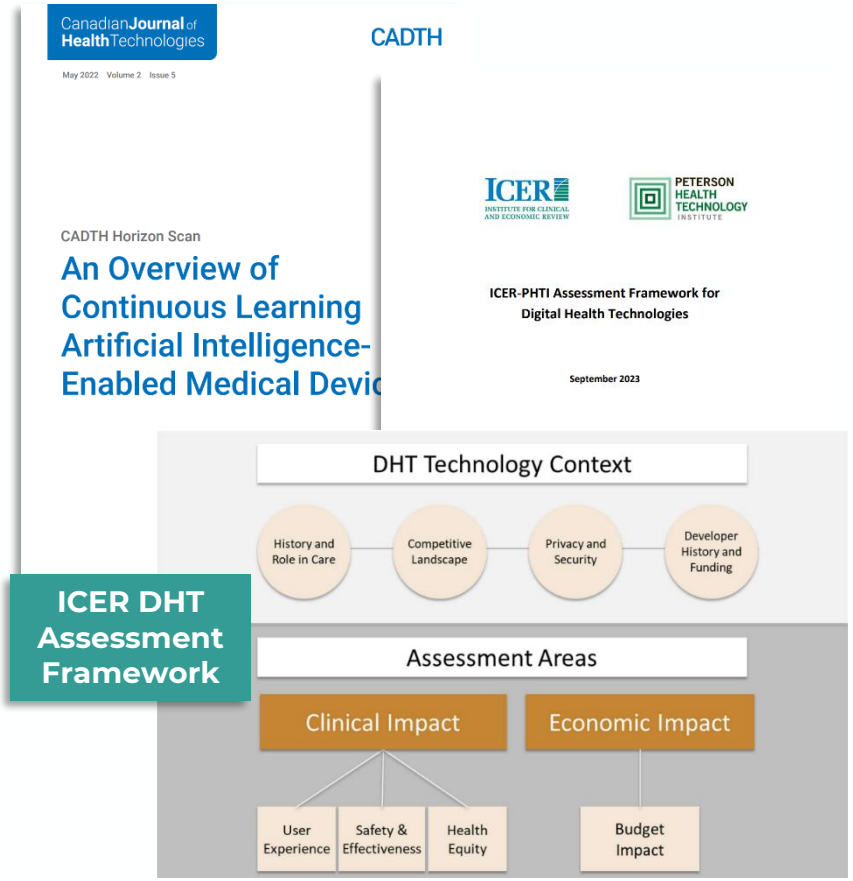
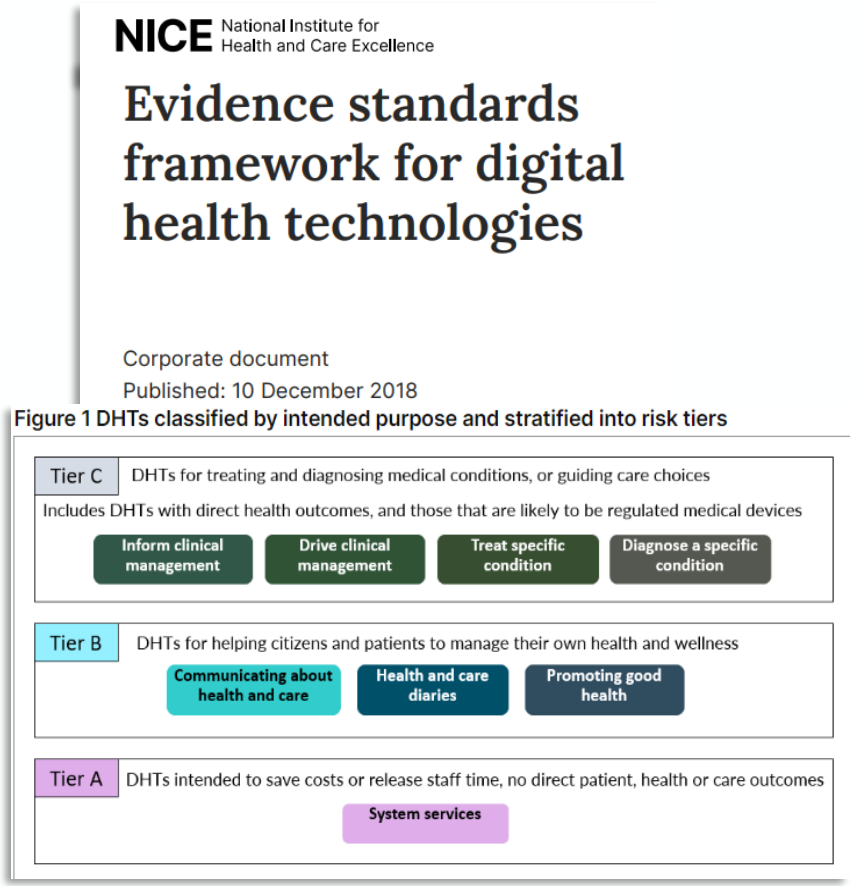
More Resources: Digital Health HTA Processes



ICER DHT Assessment Framework



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