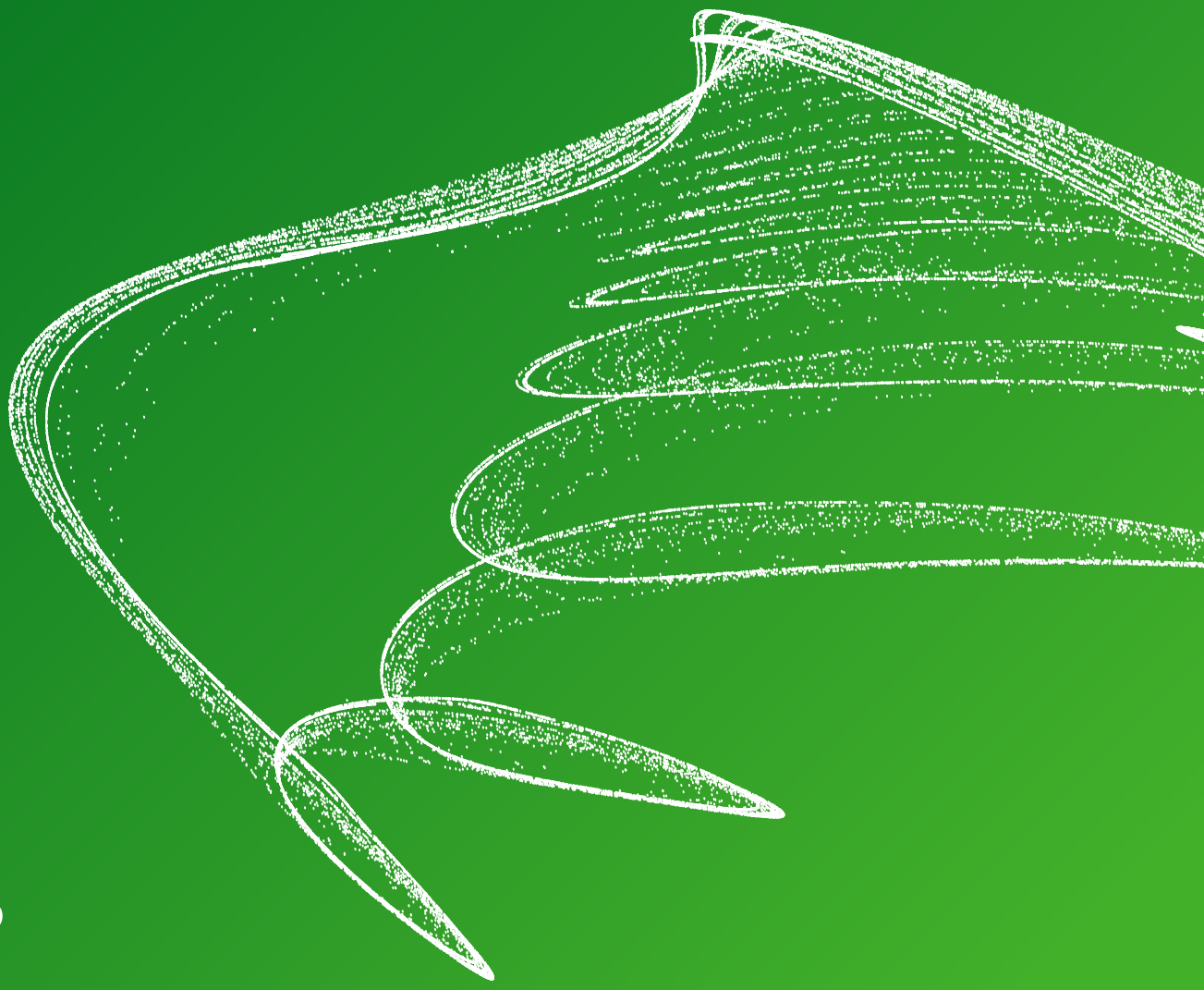
IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

Digital Health Trends 2025

Business Models, Evidence Requirements, and Revenue Opportunities



DECEMBER
2025

Introduction

Digital health stakeholders — including developers, policymakers, payers, and providers — are actively shaping and accelerating the adoption of digital health solutions. Driven by the promise these tools offer to optimize care and reduce costs, as well as recent commercial challenges facing the sector, they are rethinking how they evaluate, approve, reimburse, and bring digital technologies to market. Developers that have struggled to scale their solutions are now diversifying their business models, consolidating to lead in specific segments, and building broader solutions that better address stakeholder needs. Policymakers are refining national approval pathways and technology assessment criteria, while payers are expanding reimbursement to a wider range of digital solutions. Yet, despite this momentum, adoption challenges remain. If solutions fail to deliver compelling evidence of health benefits or cost-effectiveness, or cannot integrate with existing systems and care pathways, providers may still hesitate to embrace these technologies.

In this report, we examine how stakeholders are capitalizing on digital health innovation and addressing barriers to adoption in a rapidly evolving landscape. We explore how developers are refining their products and business strategies, and how market access and reimbursement pathways have matured. We also analyze how payer evidence requirements for digital therapeutics are changing and beginning to align globally, emphasizing the development of robust clinical data, and highlight how life sciences companies are more systematically exploring digital opportunities — partnering with technology firms and applying best practices to commercialize digital products. Across a range of digital health technologies, we take a close look at global policy shifts and other factors that will influence adoption and the future of the sector.

This report follows our Digital Health Trends 2024 report which examined the ever-expanding landscape of digital health solutions including emerging segments like digital diagnostics and digital measures.

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MURRAY AITKEN
Executive Director
IQVIA Institute for Human Data Science

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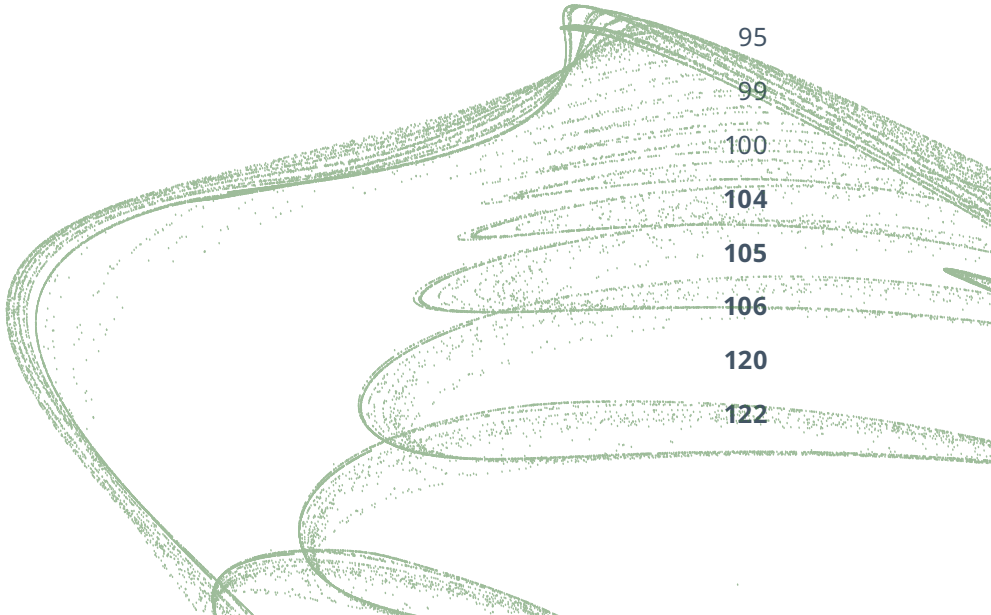

Overview

COMMERCIALIZATION

Over the past few years, innovation across the digital health spectrum has surged and more diverse solutions have entered the market. At the same time, digital health companies have found it difficult to scale their products commercially and attain sustainable revenue due to challenges securing reimbursement and widespread adoption.

In response, digital health developers have diversified their business models to expand revenue opportunities and are refining their products to better meet stakeholder needs. In addition to products, some now sell health services as digital care providers or digital diagnostic laboratories while others have adapted their proprietary software platforms to build custom solutions for life sciences companies, payers and health systems — or spin off products of different types. For instance, device companies have adapted remote-monitoring tools for use in clinical development and patient support programs.

As the market environment grows increasingly competitive, companies have also been consolidating to lead in specific segments and have expanded both horizontally and vertically to build better and broader end-to-end solutions that appeal to specialist providers and employers. Building wraparound digital care capabilities for their products has also become a key strategy. Digital care providers have begun to offer solutions that include self-guided wellness apps for condition self-management alongside medical-grade therapeutic products — allowing them to move patients between different levels of care — and sometimes use AI-driven clinical decision support tools to personalize recommendations.

Product developers have sometimes gravitated toward direct-to-consumer and direct-to-provider business models with lower regulatory barriers for their initial launches as this allows them to obtain revenue earlier in their lifecycle while refining their products and sustainably generating data over time. For instance, they may first launch self-guided wellness apps or exempt clinical therapy tools and evolve them into regulated digital therapeutics or use them in digital care. This staged approach allows developers to refine their products while generating income and offers a potential path to scale.

REGULATION AND NATIONAL PATHWAYS

Recognizing the clinical utility and cost savings of digital health solutions, government policymakers and payers have sought to establish digital health policies that speed the path of innovative technologies to market and improve their chances of success. National approaches to reimbursing or funding digital health technologies have matured as dedicated reimbursement pathways for digital solutions have been developed, assessment frameworks have been formalized, and the number of digital solutions leveraging those pathways has grown.[1]

Key elements of these policies are beginning to align globally: Countries are taking a staged lifecycle approach to evidence requirements, creating accelerated reimbursement opportunities, supporting high-quality

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evidence generation and aiding their integration into care. Several countries — including the UK, Belgium, and the Netherlands — now conduct health technology assessments of multiple digital health solutions for a specific medical purpose and may then recommend and/or reimburse several within the category.

As new accelerated pathways have launched, opportunities for faster market entry and reimbursement have become available to digital health products of increasingly diverse types and applications. These include France's PECAN and LATM for digital therapeutics and telemonitoring tools, Germany's DiPA for long-term care and nursing apps, and the UK's Early Value Assessments (EVA). Many national pathways now also span digital solutions that help diagnose, treat, and monitor patients remotely — such as Germany's DiGA pathway, Korea's Integrated Review and Assessment System (IRAS), Belgium's mHealth Pyramid reimbursement pathway, and the UK's new HealthTech pathway. However, in Belgium, as in France, only remote patient monitoring (telemonitoring) solutions have so far achieved reimbursement. In Belgium these include eight monitoring solutions for heart failure patients, and in France, three were granted early reimbursement via PECAN for cancer and post-rehab back pain and devices from nearly 30 companies gained reimbursement via LATM across five chronic diseases.

Finally, existing pathways are also being refined through policy updates to ensure the full value of digital technologies can be realized in practice and to incentivize market entry. In Germany, for instance, the DiGA pathway was recently revised to include higher-risk devices to support telemonitoring, require rapid dispensing of apps to patients and e-prescribing, introduce partial value-based payment, and set maximum reimbursement prices by therapy area.

Each national pathway has distinct strengths: the UK's NICE Guidance spans the broadest scope of digital product types; pathways in Germany, France, and Belgium provide early access to national funding; billing codes in the U.S. facilitate reimbursement within care; and Digizo.nu in the Netherlands supports scale-up. In the UK, NICE is also leading efforts to identify the optimal care setting for digital technologies and has published over 20 Early Value Assessments, recommending more than 47 solutions for use within the NHS.

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REIMBURSEMENT

In the United States, a multiplicity of payers makes it challenging to scale reimbursement. The creation of billing codes has played a central role in supporting the integration of digital solutions into care by facilitating payment to healthcare providers for the use of digital tools and health services that employ them. There are now 117 billing codes in the U.S that tie specifically to the use of software-based technologies and more than 300 that facilitate their use and that of mobile solutions. These include, with some overlap, approximately 77 codes for AI-enabled software-based tests used in diagnosis and risk assessment (several at the point-of-care), 27 for SaMD/SiMD therapeutic mobile devices, and 10 for digital care programs. Separately, around 47 codes support billing for Communication Technology-Based Services (CTBS) and other telehealth or telemedicine services. As a result, reimbursement opportunities vary

by solution type, payer, therapy area, and care setting. Medicare leads in covering remote monitoring services, while commercial payers lead in covering software-based devices like digital therapeutics and digital care programs, though overall reimbursement remains limited. Select digital therapeutics with robust evidence are now viewed by commercial payers as medically necessary but some require proof of continued patient compliance and clinical outcomes improvement to reimburse. Employers also remain an important source of funding for digital care programs which they provide as wellness benefits to employees to address concerns such as insomnia or pain or to support mental health. Some leading companies are successfully scaling with this business model. At the federal level, the Department of Veterans Affairs has actively piloted digital health technologies and negotiated pricing contracts for at least 40 solutions — some of which notably shift patients from treatment to maintenance phases of therapy.

Recent CMS policies have expanded opportunities for digital health solutions not classified as durable medical equipment to gain Medicare reimbursement as supplies and services incident to a clinician's treatment plan. In 2025, CMS created its first "contractor-priced" G-codes for digital health devices, enabling care providers to "buy and bill" for digital mental health treatment devices (i.e., digital therapeutics) incident to a behavioral health treatment care plan and is exploring the value of creating similar codes for other digital solution types. Medicare continues to lack a clearly defined benefit category for Software as a Medical Device (SaMD), under which many digital health solutions are currently classified — a gap that the reintroduced proposed legislation seeks to address. The Access to Prescription Digital Therapeutics Act would formally establish a distinct benefit category for SaMD, while the American Medical Innovation and Investment Act of 2024 would revise the interpretation of existing benefit categories to better accommodate SaMD. If either passed, they could facilitate coverage for innovative SaMD breakthrough devices under the Transitional Coverage for Emerging Technologies pathway, launched by CMS in August 2024, and under the proposed Ensuring Patient Access to Critical Breakthrough Products Act, which would mandate temporary coverage before full evidence is available.

CMS's goal to shift Medicare to value-based care by 2030 may further incentivize the adoption of digital tools and open new opportunities for digital care providers. The introduction of new care management codes that support team-based care marks an early step in this direction, allowing services to be delivered by non-physician clinical staff, such as health coaches, and several digital care providers already bill using them. A total of 56 billing codes used in digital care allow non-physician staff to deliver services including online E-visits, remote monitoring (RPM/RTM), physical rehabilitation and exercises, and various disease management programs. Claims for codes that permit incident to billing for services grew 36% from April 2024 to April 2025, compared to 10% for those directly billed by non-physicians, highlighting the importance of team-based care models.

Globally, reimbursement pathways continue to be refined. As policymakers compete to accelerate market entry of foreign-developed digital health technologies into their markets, they have sought to establish digital health policies that provide more sustainable funding. For instance, the United Kingdom plans to evolve its new unified NICE HealthTech Programme into a funded reimbursement pathway in 2026 that would nationally commission promising cost-efficient solutions and Japan has introduced pricing incentives for products that enter its market early.

The time it takes for digital therapeutics manufacturers to see revenue varies by geography but may be accelerating. In Germany, digital therapeutics can gain provisional reimbursement in as little as 2.5 years from company incorporation and permanent reimbursement within four years from the start of evidence generation (as of December 2023). In other markets, timelines range from 5.5 to seven years for initial reimbursement and up to ten years for permanent coverage.

EVIDENCE GENERATION

Evidence generation for digital solutions has rebounded since the post-pandemic dip, with growth led by efficacy studies — highlighting the importance of demonstrating value across stakeholders. However, health economic studies continue to lag despite the growing need to produce evidence of cost-effectiveness for payers. While evidence requirements for reimbursement vary by geography, they are beginning to align across key markets. Payers typically expect developers to demonstrate benefit through one or more randomized controlled trial, include the local population in studies, and compare solutions against the standard of care. Notable country-level differences remain, with mature countries seeking additional proof of continued patient use and efficacy in expected care settings. The formal or informal requirement in most geographies for randomized trials with local or locally-representative populations underscores the need for a global evidence strategy to manage costs and optimize trial design. Increasingly, payers are codifying expectations through national-level evidence criteria, while care organizations may impose additional requirements to ensure a solution's operational fit and ability to integrate with current systems.

ADOPTION

Health system adoption of new innovations is often slow, with integration into traditional care models taking time. In digital health, embedding complex solutions into care requires delivering value to a broader range of health system partners, making it critical to understand the multi-dimensional needs of each stakeholder. This can help developers overcome adoption barriers and refine their offerings.

Adoption has grown in countries with mature digital health policies, where standalone digital therapeutics are increasingly prescribed to supplement outpatient care. However, many other countries still lag in uptake. Healthcare professionals expect digital technologies to deliver multiple benefits — including improved patient engagement, enhanced monitoring, and reduced stigma in care access — but believe credibility must be further established within the medical community by providing high-quality evidence. Uncertainties around reimbursement and how patients will adapt to the new experience are also key barriers.

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The emergence of digital care providers that deliver services mainly through telehealth is a key driver of adoption. Rather than adopting digital solutions themselves, providers increasingly refer patients to dedicated digital-first care programs for rehabilitation and disease management. Where digital tools are successfully evolving existing care pathways, pilot studies and pragmatic trials have helped to gain the necessary clinician buy-in, demonstrate value, allay stakeholder concerns on data use and efficacy, and produce additional evidence of cost impact.

Health system integration is also a critical success factor. Providers and health systems expect solutions to minimize added workload, integrate smoothly into existing workflows and feed data back into patient records, making it critical for developers to capably ensure interoperability with EHRs, support billing, and align with traditional care pathways.

PARTNERSHIPS

Leading life sciences companies are taking a more systematic approach to digital health investment, conducting portfolio-wide assessments of value and feasibility across solution types that support diagnosis, therapy, and monitoring. Digital health tools have traditionally been used to add value across the lifecycle of medicines — differentiating brands, addressing specific portfolio needs, de-risking clinical development, and improving the performance of medicines.

For example, sensor-based monitoring devices that collect real-world data are often used in clinical development to enhance disease understanding and better shed light on patient experience and outcomes during treatment with investigational medicines. Partnerships with device makers enable the creation of new digital endpoints using continuous data collection that offer to yield more precise endpoints, accelerate trials, and reduce costs. FDA's draft guidance on Prescription Drug Use-Related Software has also renewed interest in digital solutions that deliver value beyond the pill, by offering a lower-risk path to launch software alongside therapies.

As life sciences companies increasingly view digital tools as a means to improve patient outcomes and fill portfolio gaps alongside traditional therapies, they have invested in digital therapeutics, sensor-enabled monitoring solutions, diagnostic aids to speed diagnosis, and AI-enabled clinical decision support tools. Patient support ecosystems and branded platforms that improve access and enhance the patient experience are emerging as a new focus, integrating telehealth, online pharmacies, and digital care services.

As funding and reimbursement pathways continue to evolve, the potential return on investment for each product type and option will shift over time. This makes it increasingly important to consider the time horizon for each solution to become scalable and economically sustainable in alignment with key product aims. In this context, partnering has become a critical strategy for life sciences companies seeking to bring digital offerings to market. Selecting device partners with the right capabilities to co-develop digital products in the right timeframe or ahead of launch is essential.

Strategic agreements with local partners also offer to accelerate the launch of existing digital products in new markets. In some countries like Japan, life sciences companies themselves have emerged as such key commercial partners to help navigate local processes and expand reach.

Finally, to overcome market barriers for digital solutions, life sciences companies are building go-to-market strategies similar to those used for traditional medicines — actively preparing the market for launch and leveraging data to guide product rollout and monitor adoption.

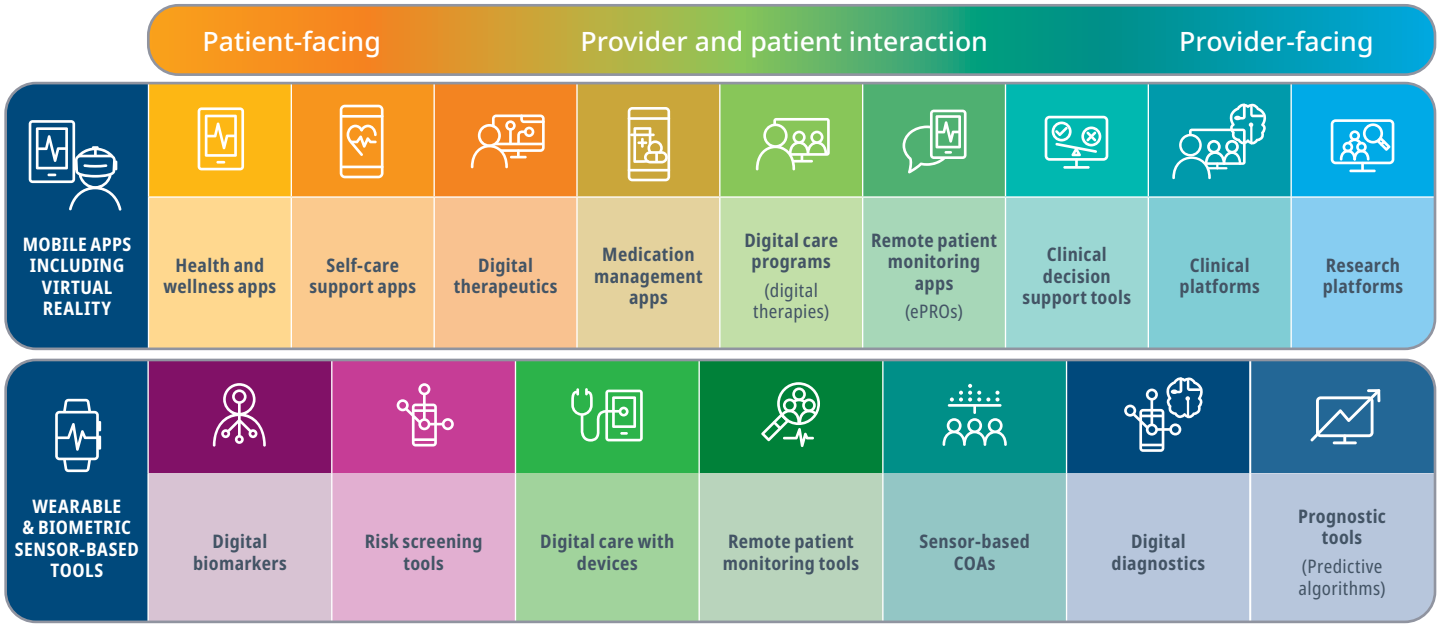
Commercialization of digital health technologies

+ **In response to commercial challenges, many digital health developers that were initially developing standalone digital therapeutics or point-solutions have diversified their business models to expand revenue opportunities.**
+ **In addition to products, developers now offer health services as digital care providers or diagnostic laboratories, repurpose their platforms to spin off varied solution types, build custom offerings for providers, payers, and life sciences companies, and adapt monitoring tools to support clinical trials and patient support programs.**
+ **As the market grows increasingly competitive, companies are consolidating to lead in specific segments and expanding both horizontally and vertically to build broader end-to-end solutions that better meet the needs of employers and other stakeholders.**
+ **Digital care providers have begun to offer solutions that include self-guided wellness apps for condition self-management alongside medical-grade therapeutic products — allowing them to move patients between different levels of care — and sometimes use AI-driven clinical decision support tools to personalize recommendations.**
+ **Business models with lower regulatory barriers— such as direct-to-consumer, direct-to-provider, and digital care using condition self-management tools — have enabled developers to earn early revenue, refine their offerings, and sustainably generate data to evolve solutions toward regulated products.**

A CHALLENGING ENVIRONMENT

The landscape of digital health innovation has expanded and diversified over the past few years, evolving into more defined market segments and areas of innovation. As newer sensor-based health assessment tools such as digital diagnostics have joined more mature digital therapies, solutions now assist patients and physicians across the full patient journey from preventative self-care to risk assessment, triage, diagnosis, treatment, and monitoring — offering to accelerate this journey and improve outcomes (see Exhibit 1 and IQVIA Institute's Digital Health Trends 2024 report).[1]

Exhibit 1: Segments of digital health and their use by stakeholder



Source: Adapted from: Digital Health Trends 2024: Implications for Research and Patient Care. IQVIA Institute for Human Data Science, December 2024.

However, even as innovation and interest in digital health have remained high, digital health developers faced a challenging commercial environment over the past two years and attaining success in this evolving market has not been straightforward. Even groundbreaking digital therapeutics companies have struggled to turn a profit and scale in the market, leading to multiple exits and restructuring.[1] As a result, continued steps have been taken by developers, providers, payers and policymakers to spur adoption of digital health solutions as these hold the key to integrating these into patient care and research more widely. In the different sections of this report, we discuss the specific actions each stakeholder is taking to drive such integration and how the digital health market's evolution is being affected by recent policy shifts.

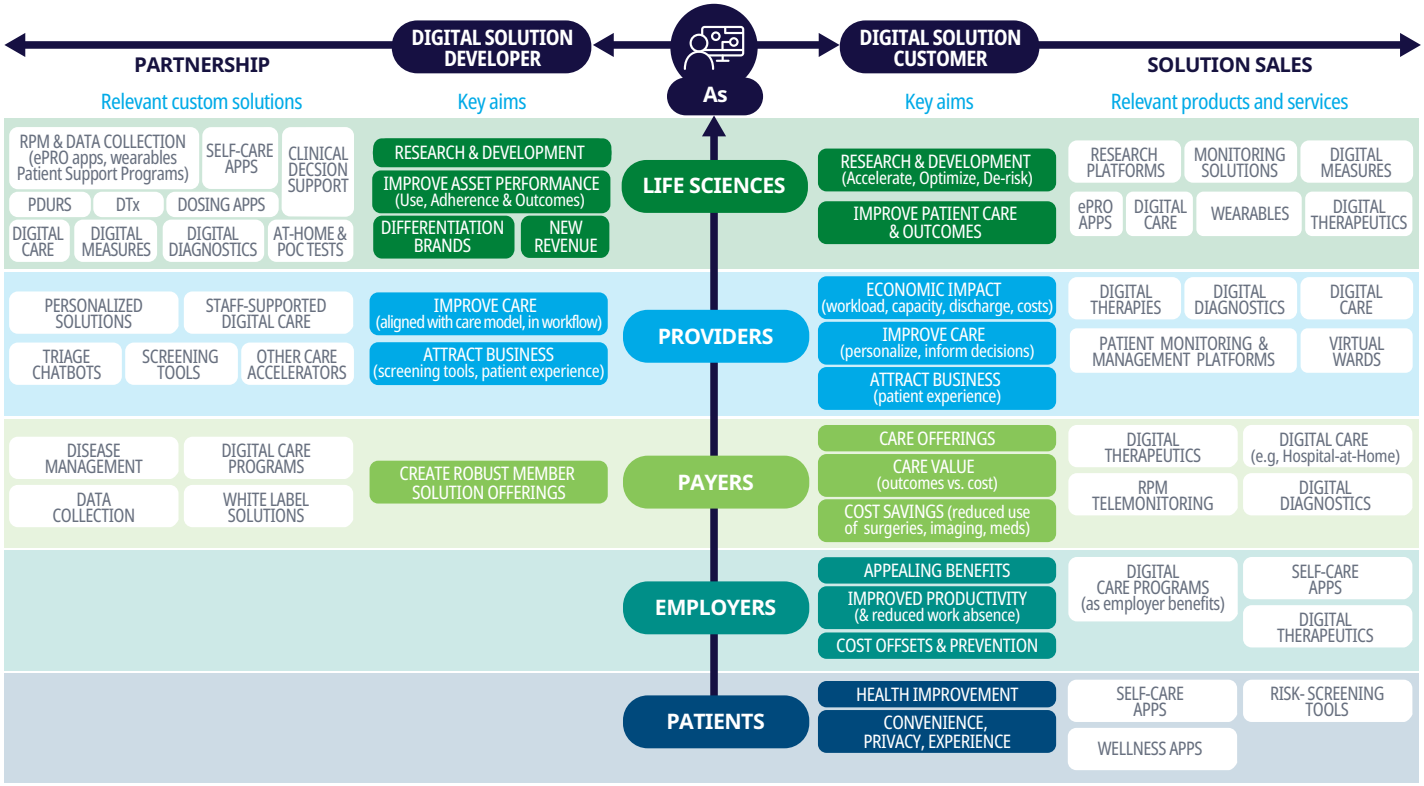
ROUTES TO REVENUE

Creating value for stakeholders

At a high level, for developers of digital health solutions to generate revenue, they can market solutions (products and services) that health system stakeholders can purchase, prescribe, license, or reimburse, or through partnerships they can adapt their digital health platforms to create custom solutions for stakeholders to market or use in their business (see Exhibit 2). The solution types that stakeholders seek to purchase or develop are driven by — and sometimes vary based on — their key aims.

Life sciences companies, for instance, now seek out a wide range of digital health products, often to add value across the traditional lifecycle of medicines. They look to new digital tools to optimize clinical development through improved measurement and health outcomes monitoring (using wearables, digital measures and endpoints, remote monitoring tools and research platforms)[1] and seek to improve the market performance of existing medicines. By developing their own solutions or through partnerships they may also seek to provide differentiation for their company's

Exhibit 2: Types of digital health solutions and how they align to key stakeholder aims (non-exhaustive)



Source: IQVIA Institute; Jul 2025.
Notes: Exhibit provides key examples within in each category and is non-exhaustive.

products (see Opportunities and partnerships section). For instance, they may develop and validate new digital endpoints to support the development of investigational products and are increasingly seeking opportunities to enhance the value of their therapeutics by utilizing apps (PDURS, dosing apps) to improve medicine use and adherence, improve health outcomes for patients receiving therapies, or address unmet needs by treating disease via new mechanisms (e.g. DTx). Increasingly, provider-focused solutions to speed diagnosis or inform prescribing are of interest (e.g. clinical decision support tools and digital diagnostic aids).

Provider organizations may likewise serve both as direct customers for standalone digital health products and as partners in bespoke solution development. Clinics and health systems have notably adopted innovative therapeutic solutions that improve patient care and outcomes while offering engaging or personalized care experiences for patients (e.g., digital therapies and VR-based rehabilitation tools). They have also sought out tools that can reduce workload or have positive economic impacts (like clinical patient management and monitoring platforms) or help to attract business and accelerate patient care (like tools for screening and triage). For instance, health systems have partnered with developers of symptom assessment apps and triage chatbots (e.g., Ada) to drive business to their institution and direct patients to appropriate clinicians in their health system.[2] However, in other cases, health systems have preferred to partner with developers to create solutions tailored to their standard pathways, and sometimes later spin these off as a new company.[3,4]

Business models for digital health solutions

Although direct product sales under payer-driven reimbursement models were initially expected to be the key route to revenue for digital therapeutics companies, other business models have emerged and become important routes to expand revenue and build a sustainable business (Exhibit 3). To capitalize on these opportunities, digital developers have been actively adapting their solutions to better serve employers, providers, and enterprises (such as life sciences companies) and pursued multiple business models in parallel.

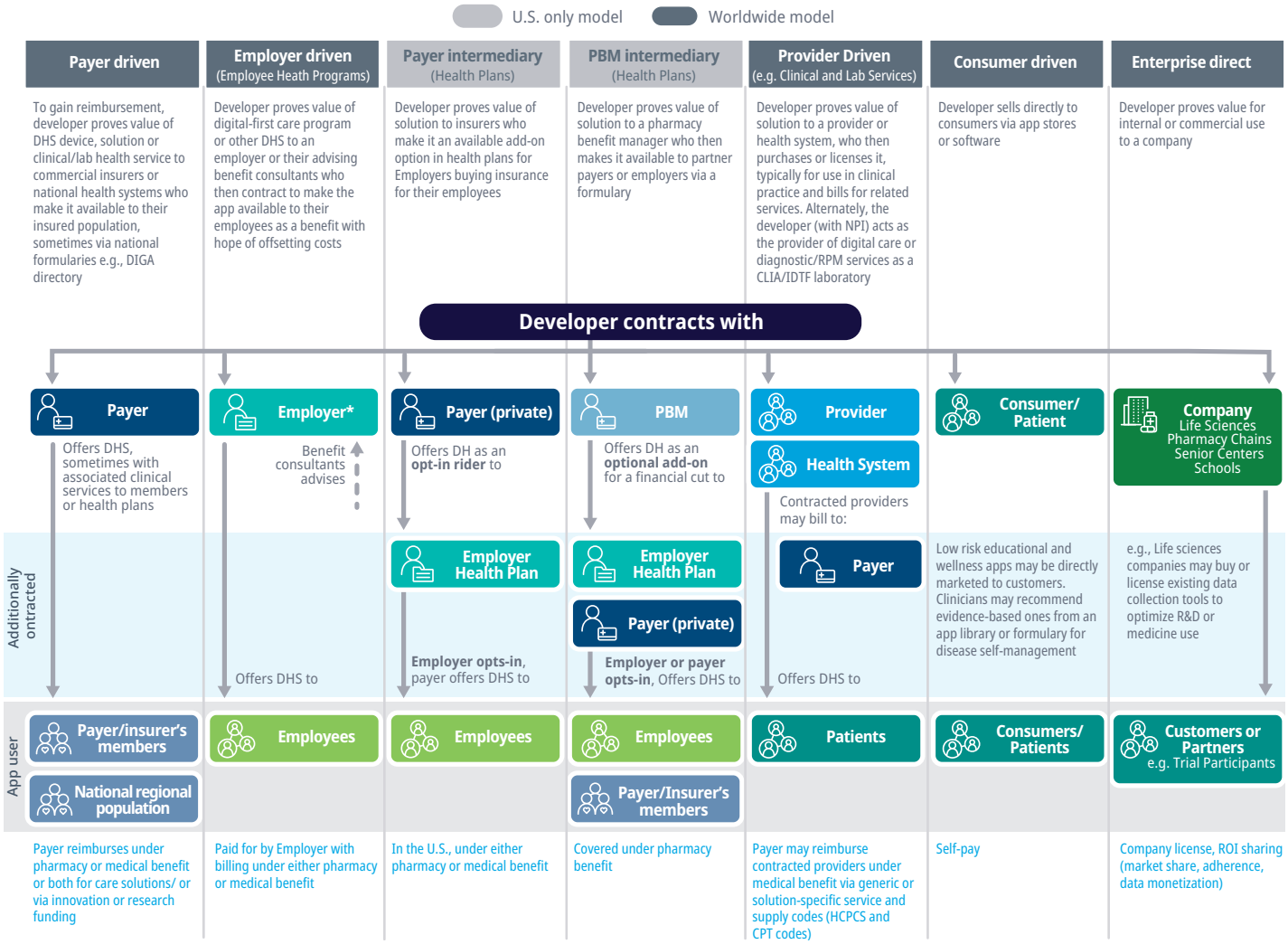
These include the following key business models:

Payer driven

With payer-driven reimbursement, manufacturers receive negotiated payment for digital solutions when these tools are prescribed to patients or used by providers in care delivery. As payers gain a clearer understanding of the clinical utility and cost-saving potential of digital health solutions, a growing number of countries with public payers have established national reimbursement pathways to accelerate adoption (see Maturity of national pathways, page 27), and individual payers have agreed to reimburse select solutions. These pathways have enabled digital tools to secure national reimbursement — initially prescription digital therapeutics (PDTs) under Germany's Digitale Gesundheitsanwendungen (DiGA) and are other pathways have been set up in France, Belgium, United Kingdom, Korea, and Japan that include remote patient monitoring solutions (RPM) and other product types.

Solutions able to demonstrate health benefits have benefitted from the creation of these national approval pathways and there are now more than 140 prescription digital therapeutics (DTx) approved/recommended globally for patient use at home.[1] These are helping address unmet needs, equip providers with new tools to improve outcomes, and close care gaps caused by limited provider availability. However, despite gradual growth in uptake globally,[1] developers still face challenges in markets like the United States, where multiple payer types and case-by-case decisions by commercial payers make it difficult to secure consistent revenue and scale reimbursement opportunities.

Exhibit 3: Worldwide business models for digital health solutions



Source: IQVIA Institute; Jul 2025.
Notes: Exhibit provides key business models and is non-exhaustive.* Typically self-insured employers.

Provider driven (e.g. clinical and lab services) model

As a result, business models that reimburse for clinical care and laboratory services enabled by digital tools have grown in importance. Under these provider-driven models, health systems, provider organizations, and clinicians may acquire or license digital tools for clinical use and bill payers each time they are prescribed or used. This model has contributed to broader adoption, with more than 220 clinical therapy tools now in use globally across blended and virtual care settings.[1] In the U.S., some developers themselves have obtained organizational National Provider Identifier (NPI) numbers to become digital care providers and bill using such codes, or registered as independent diagnostic testing facilities (IDTFs) or Clinical Laboratory Improvement Amendments (CLIA)-certified labs to provide AI-enabled diagnostic testing or monitoring services using digital tools they own.

Billing codes in the U.S. — and similar codes in other countries — enable optional payer reimbursement for these services. CMS' Healthcare Common Procedure Coding System (HCPCS) allows direct billing for certain durable medical equipment and now includes codes for

the "supply" of digital mental health treatment devices (e.g., prescription digital therapeutics) for Medicare beneficiaries. This enables a "buy and bill" model, where payer reimbursement partially offsets the cost of acquiring or licensing digital tools (see Reimbursement and uptake in the United States) and may expand access to FDA-authorized DTx and their associated care programs.[5] For example, Swing Care (Swing Therapeutics) announced it would integrate SleepioRx — reimbursable under the new policy — into holistic care for Medicare patients with fibromyalgia, just one month after the codes were released.[6]

Employer driven

Payment for digital solutions — often used within digital-first employee health programs — can also be gained by demonstrating the ability to offset costs or improve productivity. It is now common to find one or more digital care programs offered as a wellness benefit at large, self-insured companies, with manufacturers sometimes directly contracting with employers (employer-driven) and sometimes with benefit managers or payers to be included as an offering.

Payer intermediary and PBM intermediary

In the United States, another model has emerged in which developers contract with payers or pharmacy benefit managers (PBMs) to have their solutions listed on digital formularies. These solutions are then offered to health plans as opt-in riders or add-ons and may be integrated into payer data infrastructure to facilitate return-on-investment measurement. A 2024 study by the Peterson Health Technology Institute found that approximately 60% of U.S. health plans and employers (n=332) procure access to digital solutions through formularies, and around 30% do so via PBMs, in addition to direct contracting.[7]

Consumer driven

Sales of consumer digital wellness apps, self-management courses, non-prescription digital therapeutics (NDTs), and wearable devices continue under the direct-to-consumer (DTC) model, with patients paying out-of-pocket. Approximately 337,000 digital health apps now compete for consumers (patients and providers) on app stores and around 10,000 focused on specific diseases.[1] Creating a consumer-facing app is often the first step in developing more robust health solutions that may later be offered as premium or regulated versions, and this staged development may help establish a user base and generate early evidence.

Enterprise direct

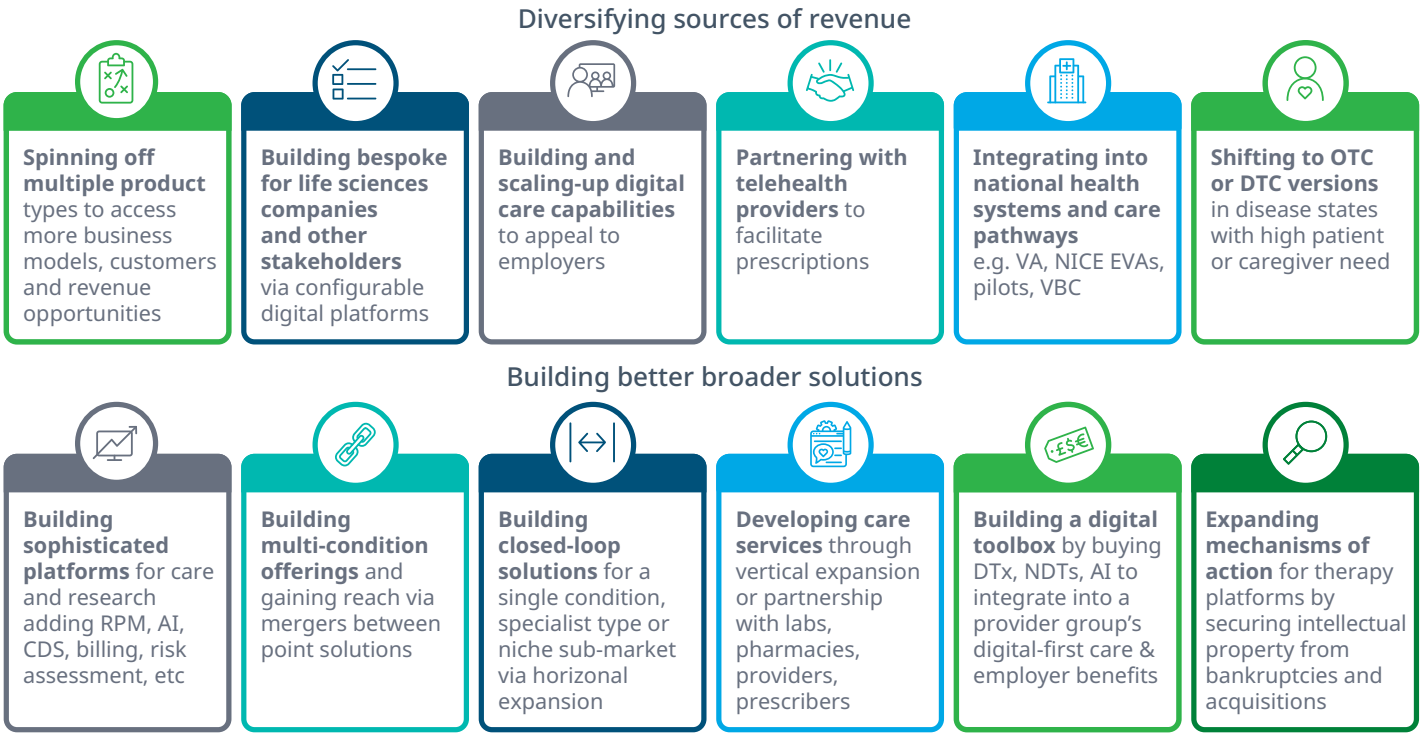
Finally, developers can sell their solutions directly to other businesses to support their internal or commercial use. Already many developers of remote monitoring tools have adapted their solutions to serve the Life Sciences research market (for instance as research apps or platforms) but senior centers and educational facilities are also consumers of wellness solutions focused on memory and attention.

TRENDS IN BUSINESS MODELS

Diversifying sources of revenue

While many digital health companies initially developed tools like digital therapeutics with the intent to sell them as standalone products, in this young market most have found it lacking as a sole route to revenue. To build more resilient businesses, many are now adapting their solutions to support multiple business models in parallel, expanding potential routes to commercial success. Developers are also evolving their products to build better, broader solutions — packaging sensor devices, apps, telehealth, and software platforms together in new ways — that increase the case for health system adoption and better serve providers, employers and other stakeholders. Some are horizontally and vertically integrating to position themselves as leaders in specific segments (Exhibit 4).

Exhibit 4: Trends in digital health business models



Source: IQVIA Institute; Oct 2025.

Spinning off multiple product types

By repurposing their early digital products and platforms, developers have begun marketing related offerings as distinct solution types — each subject to different regulatory requirements, appealing to different customer segments, and unlocking diverse revenue opportunities. These also sometimes address different phases of condition management like prevention, treatment and maintenance.

Developers of therapeutic solutions, for instance, may simultaneously offer:

- **Self-guided educational content**, such as non-prescription therapeutic apps (NDTs) or online courses, to support patient self-care, behavior change and prevention of specific diseases, or as an adjunct to usual medical care
- **Digital care programs**, where the company's employees or partner providers use apps for condition management and are sometimes offered as employer benefit solutions
- **Approved prescription digital therapeutics (PDTs)** by adapting components of the solution to gain approval as guided prescription for treating a disease and its symptoms.
- **Clinical therapy tools**, which providers and health systems can license for use in clinical settings to deliver more personalized care experiences.
- **Bespoke therapeutic solutions**, developed for other life sciences companies or stakeholders, tailored to specific clinical or commercial needs.

Sensor-based monitoring tools may similarly be offered as patient-facing apps for self-monitoring, as remote patient monitoring platforms for providers, as hospital-at-home care services, or as research tools for data collection in clinical trials and digital biomarker development — thereby serving life sciences companies.

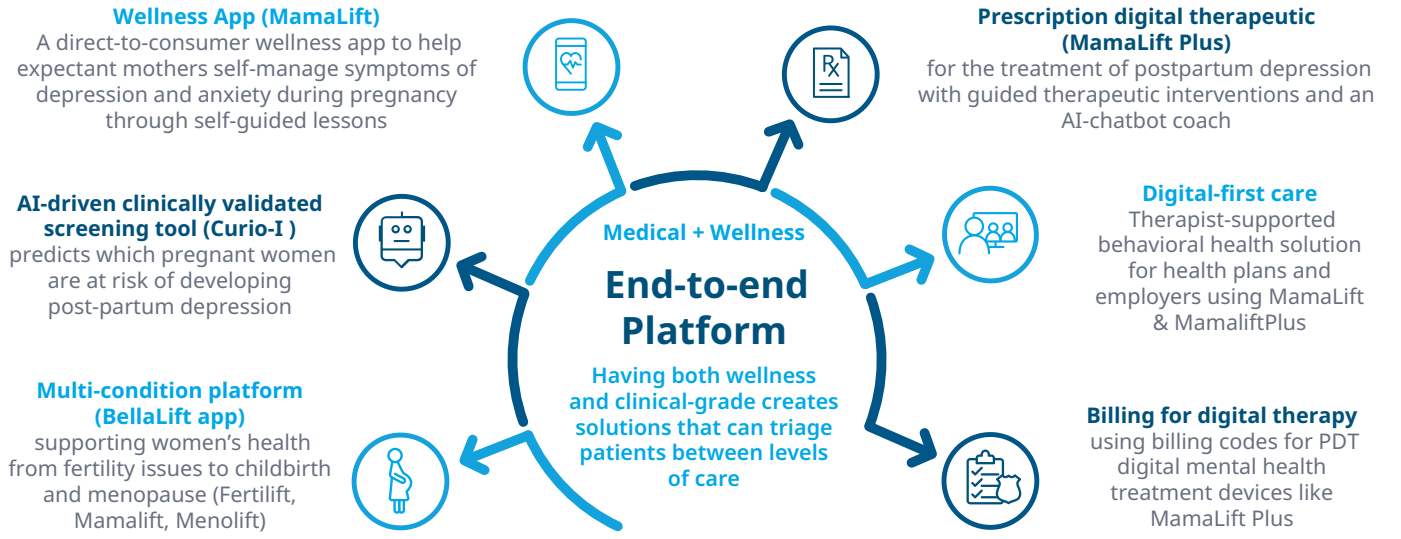
As an example in the therapy space, Curio Digital Therapeutics offers a suite of women's health solutions that span product types through its BellaLift platform,

with modules supporting fertility (FertiLift), childbirth (MamaLift), and menopause (MenoLift). Initially marketed as a direct-to-consumer wellness product, MamaLift provided self-guided lessons to help expectant mothers manage symptoms of depression and anxiety during pregnancy[8] and was also used within a therapist-supported digital-first care solution for provider and employer accounts.[9,10] Following FDA clearance, the company launched MamaLift Plus — a prescription digital therapeutic delivering guided interventions for postpartum depression, supported by an AI chatbot coach. Marking a broader industry shift, Curio additionally embedded a clinically validated, AI-driven screening tool — Curio-I — into its platform to identify women at risk for postpartum depression and triage them to the appropriate version of the solution: wellness, prescription, or therapist-supported (Exhibit 5).[11] Prescriptions for the device now appear to be facilitated via its Curio Care Network of providers and integrated into its digital-first care model.[12–15]

For health plans and employers, this trend notably enables Curio and other developers to offer "stepped" care solutions with both wellness and clinical-grade digital treatments that enable patients to move between different levels of care. They may do so based on individual need or as they shift to a maintenance phase of therapy. Using different types of digital tools — as Big Health similarly does with Daylight and its guided PDT DaylightRx[16] — may help digital care providers take

> *"Following risk identification, the company triages patients to the MamaLift platform, offering a continuum of care that starts with general wellness support and can progress to the MamaLift Plus prescription product for more intensive intervention. MamaLift's proprietary clinical logic also escalates to trained therapists as and when needed."*
>
> *— Frost & Sullivan, 2024 Best Practice Award[18]*

Exhibit 5: Company example: Curio Digital Therapeutics' BellaLift women's health platform



Source: IQVIA Institute; Mar 2025.
Notes: Information displayed was current at the time of collection and reflect the Institute's interpretation of the company's past moves and overall trends.

advantage of new reimbursement opportunities as they emerge. For instance, PDT versions like MamaLift Plus can now be used and reimbursed within digital care using the new HCPCS supply codes for FDA-approved digital mental health treatment devices.[17]

Building bespoke for stakeholders via platform technologies

Developers diversify their digital offerings by reusing and repurposing their platform technologies. A digital health product's platform includes software modules that serve distinct functions — such as delivering therapeutic content, guiding exercises, educating patients to support disease management, collecting ePROs, monitoring outcomes, or facilitating billing — along with pre-built user interfaces, integrations, and AI or analytic algorithms. These various parts can be adapted to create new digital solutions.

Companies that have launched successful digital products now adapt their platforms to create bespoke or white-label health apps, digital therapeutics, PDURS, and care programs for a range of stakeholders. For example, Sidekick Health markets its platform to life sciences companies as a route to bring their own digital products to market. Early platform developers like Glooko and Welldoc now similarly offer white-label solutions adapted to a health partner's "brand, chronic care program or ecosystem," to support additional chronic conditions, or to enable clinical study data collection and management.[19,20]

Digital therapeutic developers, such as HelloBetter and Selfapy, have repurposed their own platform technologies to launch multiple DiGA products in Germany. Re-targeting the mechanisms of action they deliver to new disease areas, they are often able to develop a second product more rapidly than the first. This strategy mirrors how biopharma companies use a single drug delivery platform to develop therapies across mechanisms and diseases — a "biotech-like approach."[21] For instance, Click Therapeutics describes itself as having "shared platform technologies with novel cognitive, behavioral and neuromodulatory mechanisms of action"[22] and Mahalo Health positions its platform as having "digital therapy building blocks" that snap together like Legos to create digital companions.[23]

The same applies to patient monitoring and risk assessment platforms where functions that pull in and analyze data from sensor-based devices have been pre-built and are of interest to stakeholders both for care and clinical trials. Some clinical platform developers pursue up-front regulatory approval for their platforms and functional modules. Huma adopted this strategy in 2023 — securing approval for its Class IIb patient management platform in Europe before building disease-specific applications that support monitoring across conditions and patient ages. The platform includes modular functions — such as patient education and medication management — that integrate with external devices to collect data and apply algorithms to predict risk, assess prognosis, or support diagnosis.[24] Ultimately, for developers, a "platform" approach helps underly a commercial strategy that spans product types and sources of revenue and also enables them to market and create bespoke products for multiple stakeholders.[19]

Building digital care capabilities

As digital care has found growing adoption among employers and health plans — and helps to address low adoption among traditional providers — developers have rapidly built virtual care and telehealth wraparounds for their solutions including digital therapeutics and disease self-management apps. Some developers have become provider organizations and branded their solutions as "digital-first" care, while others have partnered to offer health support and behavioral coaching services. Companies have scaled up these digital care wraparounds in several ways, including:

- **Hiring coaches** as early entrants like Noom and Kaia did around 2017 to create digital care programs for weight management and musculoskeletal physical therapy, respectively.[25,26]

- **Merging with digital care companies**, as Headspace did with Ginger in 2021 to offer mental health coaching.[27]
- **Becoming a care company by obtaining a Type 2 organization NPI** to submit claims to payers under the company's name, receive payments, participate in healthcare transactions (e.g., deliver digital care services, send referrals, patient records, work with clearinghouses) and meet payer and health network credential requirements.[28] As many have done and continue to do like Curio Digital Therapeutics in 2022.[29]
- **Partnering with coach service providers** that offer APIs to integrate their coaching into digital products to build out or scale up their digital care wraparound as Twill (now Dario) did with YourCoach Health to better serve the employer market.[30]
- **Becoming a Management Services Organization (MSO)** to create a network of affiliated but independent providers who prescribe through the developer's branded platform. MSOs offer administrative and tech infrastructure to medical practices and healthcare facilities and may license telehealth platforms that enable independent providers to deliver care and prescribe the company's digital therapeutics or other products (if appropriate). For example, Swing Therapeutics launched "Swing Care MSO," licensing its platform brand and software to affiliated providers who operate as "Swing Care" and provide telehealth services." This model potentially also facilitates access to de-identified user data.[31]

With these approaches, developers are then able to escalate patients to higher levels of care where coaches and therapists are more actively involved. Not only does provider care wraparound appear to be key element that appeals to employers and health plans but may also be a way to keep patients engaged, support their adherence (durability) and therapeutic success.[32]

Partnering with prescribers

Partnering with independent provider groups and telehealth companies has also become a common strategy among therapeutic product developers — both digital and life sciences companies alike — to facilitate clinically appropriate prescribing and avoid losing interested patients visiting the product's website. Some of these patients find it challenging to find a relevant provider and many traditional providers are still not comfortable prescribing these standalone products like prescription digital therapeutics or other digital devices due to lack of familiarity. To overcome these access barriers, Axena Health partnered with UpScriptHealth telehealth prescribers to evaluate women's incontinence symptoms and, if appropriate, prescribe newly launched Leva Pelvic Health System.[33] Relivion similarly partnered with BelugaHealth and embedded a link on their website to link interested patients to the external telehealth provider, who then reviews individual cases and prescribes solutions as appropriate.[34]

Separately, many digital therapeutics companies have also now contracted to have all prescriptions in the United States flow through a single pharmacy — for instance Rejoyn (Otsuka) is only available through CaryRx[35] — helping to facilitate prescribing, ensure prescribing instructions are clear to providers, and potentially ensure all prescription data is visible in a de-identified fashion to the manufacturer to provide insights.

Integration into national health systems and care pathways

Health systems are finding new ways to deploy and integrate digital health solutions at their care sites — often through pilots, organized research, or temporary funding. In the U.S. and UK, health systems have run pilots within research settings to determine the appropriate role for digital solutions in care delivery and confirm their effectiveness in relevant environments and populations. These engagements also create opportunities for developers to adapt their solutions to local needs and ensure products align with the needs of the healthcare ecosystem.

> *"...Deprexis will be compared to a treatment-as-usual control... to establish if results obtained in the general population sample extend to Veterans with mild to moderate depressive symptoms. .... Our long-term vision is that Deprexis can be integrated in a stepped-care approach; providing rapid intervention for individuals with mild to moderate depressive symptoms, while reserving resource-intensive treatments such as face-to-face psychotherapy for individuals with severe symptomatology."* [38]
>
> *— Elin Teague Veterans Center trial description*

For example, countries with national health systems may favor blended-care models that leverage existing staff and align with preferred care pathways. In the United Kingdom, this has prompted developers like Bold Health, tailor its Zemedy digital therapeutic offering to be supported by National Health Service (NHS) staff.[36,37] Digital mental health therapies are expected to follow a therapist-guided model and mirror NICE-recommended approaches in the UK to be considered by Talking Therapies (formerly Improving Access to Psychological Therapies) expert panels.[3] In the United States, the Department of Veterans Affairs' (VA) likewise pilots digital tools within care such as their trial of Deprexis.[38] While these pilots help health plans — and other payers — evaluate how a digital therapy could be scaled across their membership, they may also require digital therapeutics companies to be operationally strong, capable of implementing custom integrations to feed data back to institutions and take on the "heavy lifting" of deployment.

Shifting to OTC or DTC versions

While most digital therapeutic developers remain focused on building out their business-to-business models, in some disease areas where patient or caregiver demand is high, re-opening a route to sell direct-to-consumer to patients or caregivers may help expand revenue. To enable broader consumer-driven adoption, some prescription digital therapeutic devices with low risk and high consumer demand

> *"We're working with the NHS in the UK, where we can create a supported program with NHS staff. Specifically, there's the IOP program for increasing access to psychological therapies, there is an IBS track with CBT for IBS, where they have human coaches or trained psychologists, counsellors to support patients with this type of intervention. Then the patient will use our app for self-management..."* [36]
>
> *— na Mustatea, CEO Bold Health in 2021*

have attempted to shift to an over-the-counter (OTC) model or have spun off DTC versions of their content. Akili Interactive (now Virtual Therapeutics) saw limited uptake of its serious game EndeavorRx for children with ADHD as a prescription product and sought to shift to OTC distribution. While FDA approval for its Rx-to-OTC switch in pediatric populations remains uncertain, Akili did successfully file an adult version of the app as an OTC product. Initially launched as EndeavorOTC under pandemic-related enforcement discretion, it later received FDA clearance and is now marketed as Outplay ADHD for $130/year.[39] This approval may signal growing FDA comfort with making lower-risk digital devices and PDTs available OTC. However, the company's decision to mostly abandon the PDT model also suggested to developers they might be better off seeking market access as an unregulated disease self-management product or versions that could be used within digital care.

Companies with digital platforms have also adapted clinical grade content for DTC use. For instance, Welldoc introduced a non-prescription/DTC version of its FDA-cleared BlueStar Rx diabetes therapeutic in 2017, expanding access beyond prescription channels and later integrated it into a broader wellness-oriented program. More recently, digital care company Nerva Health repurposed CBT content from Mahana Therapeutics to build its consumer-facing IBS program following its acquisition of key Mahana assets.[40]

Building better broader solutions

As the digital health market grows increasingly competitive, companies are consolidating to lead in specific segments and expanding both horizontally and vertically to build broader end-to-end solutions that better meet the needs of employers, health systems and other stakeholders. Through mergers, acquisitions, and asset purchases, they gain new capabilities and grow their ability to deliver more compelling offerings. Some have enhanced their care platforms by integrating products from adjacent segments — spanning therapeutics, analytic AI-driven triage and health assessment tools, and monitoring devices — while others have launched virtual care clinics equipped with a suite of digital tools spanning multiple health conditions.

Building sophisticated clinical platforms

Over time, developers of standalone consumer-facing technologies — such as symptom-tracking wearables and self-monitoring apps — have evolved their offerings into integrated clinical platforms. These now include provider-facing portals that support holistic care management and help providers deliver personalized and efficient care. For instance, therapeutic platforms often feature advanced algorithms that support clinical decision-making, dose management, and treatment guidance. And some issue alerts when patient-reported outcomes or clinical values fall outside defined thresholds — helping providers identify patients who may need care adjustments and potentially reducing workload. By integrating into clinical workflows and offering advanced data and reporting tools — including those tied to value-based care quality metrics — these solutions deliver added value for providers, better align with health system needs, and strengthen the case for adoption.

An early example of this evolution is Glooko, which launched its Logbook app in 2011 to help patients with diabetes track blood sugar levels from fingerstick glucose meters. Over time, the platform has expanded to include a population health analytics portal for providers to identify at-risk patients, recommend insulin adjustments and monitor post-intervention outcomes. It also integrates diabetes data into EHRs, reducing the need to toggle between systems, and supports remote patient monitoring (RPM) billing by identifying patients eligible for reimbursement each month.[41,42]

Patient monitoring tools have also become more provider-friendly, morphing into sophisticated remote monitoring platforms that aggregate data from multiple devices and apply analytics to assess the health status and exacerbation risk of patients with chronic or multiple conditions. These platforms combine medical-grade

sensor devices, wearables, digital biomarkers, apps that facilitate remote performance tests and electronic patient-reported outcome (ePRO), and AI algorithms to continuously track physiologic changes — such as temperature, respiratory rate, heart rate, and blood pressure. Some platforms are device-agnostic, while others rely on proprietary hardware.

Clinicians that license these software platforms can then monitor and manage their patient populations remotely, while life sciences companies and clinical trial investigators within the research space may use research-versions of these to detect when a participant might be at risk of an adverse event such as cytokine release syndrome (CRS) or neurotoxicity in oncology and immunology trials.[43] Biofourmis' Platform, as an example, analyzes physiologic data from wearables to monitor patients with chronic conditions like heart failure, arrhythmias, pain, cancer, and sleep disorders. Its AI-driven predictive capabilities add value by forecasting exacerbations, complications, treatment response, length of stay, and readmission risk. Some leading companies have further wrapped care services around these platforms to create Virtual Wards and Hospital-at-Home, which provide continuous patient monitoring and inpatient-level care at home, supporting earlier hospital discharge.[1] For instance, Biofourmis' has a Hospital-at-Home platform featuring its Biovitals Index and other companies like Current Health (Best Buy Health), BioIntelliSense, Clinitouch, Doccla, and Huma, are active in this segment.[1]

Building multi-condition care offerings for employers

TIn the U.S., the demand for digital care solutions that address a broad range of conditions — rather than single-point solutions — has grown significantly among purchasers. According to the Peterson Health Technology Institute, 92% of employers, 88% of health systems, and 81% of health plans said multi-condition coverage said was important to them when evaluating digital health solutions and it was among the top ten attributes most widely cited as important.[7] This shift likely reflects a desire to reduce the need for custom data integrations, streamline contracting and procurement processes, and — amid growing competition — address fatigue from many point solution vendors requesting assessment.

To appeal to employers, health plans and benefit managers under a Business-to-Business (B2B) model, many digital solution providers are therefore developing comprehensive platforms that address multiple chronic conditions and behavioral/mental health needs rather than focusing on one disease area. Through mergers, acquisitions and asset purchases, they have expanded to other disease states, gained access to different product types and capabilities and added personalized coaching and peer support communities.

DarioHealth illustrates this trend. Initially focused on diabetes management, the company expanded into pre-diabetes, hypertension, weight management, and musculoskeletal care. Its acquisition of Upright Technologies strengthened its musculoskeletal offering, while acquisitions of wayForward and Twill (which had previously acquired Happify) extended its reach into virtual care deliver for behavioral, mental, and maternal health.[44] These moves have positioned DarioHealth as a full multi-condition virtual care platform.[45]

Cost containment pressures can also drive payers and employers to seek digital health providers that address specific high-cost conditions, such as obesity. As demand for GLP-1 obesity drugs has surged, payers have begun reimbursing digital weight management programs that use mobile apps to promote behavior change before initiating drug therapy or support adherence to those therapies.[46] For instance, virtual care companies like Welldoc and Noom have expanded their offerings in the weight loss space. Noom added a medication-prescribing component to its behavior change program (Noom Med), and Welldoc augmented its chronic care platform to cover weight management with digital coaching (supporting patients on GLP-1 therapy).[47–49]

> *"We are establishing pioneering relationships with industry to test innovative models of delivering weight loss services and treatments to patients effectively and safely. This may include…digital only models, where everything is done and managed online…. We will build on the success of the NHS Digital Weight Management Programme, expanding it to 125,000 more people per year and so doubling the number of people who can access it. This programme has strong evidence for delivering sustainable weight loss and delivers excellent value for money."* [50]
>
> *— Fit for the Future 10 Year Health Plan for England*

Building closed-loop solutions

Other companies have sought to establish leadership in niche markets. Some are developing end-to-end care solutions for specific specialists — such as neurologists — while others aim to comprehensively manage a single condition like chronic pain or sleep disorders by assembling integrated toolkits to screen, treat, and monitor patients.

For example, SleepUp — a digital therapeutics (DTx) platform designed to improve sleep health and manage insomnia — combines a cognitive behavioral therapy DTx approved for insomnia by Brazil's ANVISA with mindfulness-based interventions, wearable technology (a ring oximeter), a medication management module, and proprietary algorithms to analyze user data (sleep patterns, vital signs) for personalized care. It also offers provider support and has an EEG wearable headband in development.[51] Similarly, Nox Health's SleepCharge program delivers end-to-end sleep care management, while Mindset Health's Nerva solution targets digestive health.[52,53] By cutting across digital health product segments — including diagnostics, monitoring tools, and AI — these platforms position themselves as closed-loop solutions that collect data and continually refine care (Exhibit 6).

Platforms being developed for specific provider types bring together point solutions to manage patients with diverse conditions within that therapy area. For instance, the Neuroventis "neurology platform" was initially designed for clinical practice, serving neurologists and patients with epilepsy and migraine, and planned to expand to Parkinson's, stroke, multiple sclerosis, and Alzheimer's.[54] The acquisition of Neuroventis by Cascador Health in late 2024 underscores how such clinical platforms — and their patient-facing tools — are increasingly leveraged for real-world data collection opportunities in the life sciences research market and decentralized trials.[55]

Finally, some players are positioning themselves as leaders in specialized technology niches such as virtual reality (VR)/extended reality (XR), rehabilitation tools, and serious games.[56] In XR, for example, XRHealth — a U.S.-based digital care provider — has pursued a series of acquisitions to build the "largest XR therapeutics platform"."[57] Its immersive apps for clinical use and chronic pain therapy platform (which received

Exhibit 6: Product features offered on some digital care and patient management platforms

Remote monitoring tools
Wearables and ePRO apps collect physiologic/ symptom/QOL data to monitor progress and outcomes, potentially enabling use of RTM codes

Patient communities
Help patients connect and receive peer support

Waitlist support
While patients wait for higher levels of care

AI-supported personalized care plans
CDS may help generate personalized care plans

AI chatbots (education/motivation)
Personalize patient support and guide patients to relavent educational materials to enable self-care

Multiple digital tools
From self-guided tools for symptom self-management/wellness to clinical-grade tools like DTx/ VR

Virtual provider support

Closed-loop feedback
Uses AI and software to assess outcomes and patient response to treatment, suggest adjustments and refine care (e.g. training/treatment protocols, dosing)

Reporting tools for providers
Generates standard reports to help evaluate patient progress and escalate to higher levels of care including coaching

Population management and other tools that streamline workflow
Automates tasks and prioritize care to reduce clinician burden and increase capacity

Billing modules or instructions
Enable providers to bill for care services and tools through the software OR provide billing codes with clear instructions to prescribe, bill or refer

Smart phrase template
Enables care instructions to be given to patient at discharge via a provider's EMR

Digital front door/e-triage
Screen or triage patients using AI or algorithms and may refer patients to different levels of care

Free clinician access
Allows providers to explore the app, content, care flow and patient experience

Customization tools
AI creation tools allow users to write code on top of the platform & crowdsource

Pharmacy Services
To dispense medicines, DTx

Source: IQVIA Institute; Nov 2025; Compiled from multiple company websites and public sources.

breakthrough therapy designation)[58] were strengthened by its 2023 merger with Amelia Virtual Care, adding VR rehabilitation tools for clinical use.[59] With its acquisition of NeuroReality in 2024 it gained VR cognitive training and rehabilitation tools like the game-based Koji's Quest designed to support patients with cognitive impairments stemming from stroke, long COVID, traumatic brain injury, neurodevelopmental or neurodegenerative conditions, and dementia.[60] Its February 2025 acquisition of RealizedCare then expanded its capabilities in chronic pain and behavioral health, adding a triage tool to help personalize care, and the company is further developing an AI-enabled closed-loop learning technology that would adjust VR treatment based on biometric and motion data from the Apple Watch.[60–62]

This example illustrates how consolidating applications within a digital health segment can unlock multiple business models and sources of revenue: XRHealth can now deliver immersive care programs supported by digital therapeutics to health plans, offer direct-to-consumer care and wellness apps for stress, anxiety, and chronic pain, and provide a clinical platform for therapy and rehabilitation across physical, neurological, cognitive, and mental health conditions — including Parkinson's disease, multiple sclerosis, chronic pain linked to anxiety, PTSD, OCD, ADHD, and phobias. Broadening the mechanisms of action that providers can leverage from within these offerings also will likely enhance provider appeal — in this case including Virtual Reality Exposure Therapy (VRET), CBT, hypnotherapy, symptom management, cognitive training, meditation, fitness programs, and biomechanical function analysis.[60,63,64]

Developing care services

Vertical expansion — through both forward and backward integration — is becoming increasingly common in digital health, and has led to the rise of clinical and laboratory services business models. To create a care services model, some digital health companies are evolving into care delivery organizations, and provider groups have also acquired digital product developers or their technologies to become digital care companies. The resulting entities can prescribe digital tools and bill for clinical services, through a clinical services model. For instance, Amwell's acquisition of SilverCloud now enables it to offer digital mental health tools within a reimbursable care framework.[65,66]

Digital care providers have also become vertically-integrated through mergers that brought them in-house pharmacies for dispensing. PursueCare, for example, operates PursueCareRx, allowing its pharmacists to fill prescriptions internally.[67] Others have been acquired by already vertically-integrated players. UnitedHealth Group, for instance, expanded its digital care portfolio through its Optum division by acquiring both digital products and provider services — such as Sanvello (a self-care NDT), AbleTo (virtual behavioral health), Vivify (remote patient monitoring), and PatientsLikeMe (a patient community platform). Some of these assets have been integrated into AbleTo's Self Care+ offerings, an on-demand digital mental wellness program.[68] Other digital care companies also distribute their products directly as durable medical equipment (DME) suppliers, bypassing third-party distributors, or like JOGO Health and Vori Health, operate brick-and-mortar clinics to deliver hybrid virtual and in-person care.[4,69]

To build a lab-services model, some digital diagnostics companies that created AI-based algorithms to diagnose, assess risk or predict progression — have expanded to function as independent diagnostic testing facilities (IDTF) or as CLIA-certified labs. This model allows digital diagnostics firms to bill for testing and monitoring services enabled by their devices. Referring providers can prescribe device-based services or transmit captured images or signal data to centralized digital diagnostics labs, which then apply proprietary analytics or AI algorithms and bill insurers for testing under the medical benefit.

For example, in addition to AliveCor's care services for its OTC devices (KardiaCare), its acquisition of IDTF CardioLabs led to the creation of AliveCor Labs, where readings from AliveCor's ECG devices can be sent for continuous monitoring and analysis by certified technicians and delivers an end-of-study report to providers supporting diagnosis and treatment decisions.[70,71] It also allows AliveCor to bill directly for cardiac monitoring services using its KardiaMobile 6L device and offer end-to-end diagnostic and monitoring support.[72] This approach provides an alternative to selling software to health systems, which may require additional provider training or infrastructure, posing adoption barriers.

Building a digital toolbox

Both digital tools and intellectual property from bankrupt digital therapeutics companies are being purchased and repurposed for use in digital care.[73] Digital care companies are increasingly acquiring both prescription (PDTs) and non-prescription digital therapeutics (NDTs) to integrate into their care programs and gated employer solutions, often supported by health coaches.

For instance, digital therapeutics affected by the bankruptcy of Pear Therapeutics were ultimately acquired by digital care companies. Somryst, was immediately acquired by Nox Health, a sleep-care company looking to expand its digital toolbox and likely

used within its SleepCharge program for employers and health plans.[74,75] And two other Pear products, reSET and reSET-O, were temporarily lost from the market after bankruptcy, but subsequently acquired in August 2024 by PursueCare and similarly relaunched within the bounds of digital care for addiction.[73,76,77] CMS has recently expanded reimbursement opportunities for digital mental health treatment devices that are relevant in this area.

A recent example indicates that some pharmaceutical companies may also consider outright acquisitions of developers or digital therapeutic products in their key therapeutic areas. Following the demise of Mahana Therapeutics, Bayer announced it would acquire HiDoc Technologies and Cara Care in Q1 2025 — along with its Cara Care DiGA digital therapeutic for IBS in Germany — and potentially adapt the solution for its "precision self-care" initiative.[78] Whether this signals a broader trend toward life sciences companies bringing digital health IP and expertise in developing disease management solutions in-house, rather than relying on partnerships, remains unclear.

> *"PursueCare will offer appropriate patients a course of reSET or reSET-O for $90 out of pocket and will additionally seek reimbursement under remote therapeutic monitoring codes that allow providers to bill for supplying monitoring devices, including software, to patients and for tracking the progress of cognitive behavioral therapy treatment."* [76]
>
> *— PursueCare*

Expanding platform mechanisms of action

Just as biopharma companies might seek to acquire foundational drug-delivery technologies, recent bankruptcies have also offered opportunities for developers to scavenge intellectual property to broaden their own therapeutic platform technologies and gain new mechanisms of action. For instance, Click Therapeutics acquired the intellectual property of Better Therapeutics in 2024 in part to adapt AspyreRx CBT diabetes digital therapeutics to the obesity space leveraging its platform, and Nerva Health acquired Mahana Therapeutics' intellectual property in the IBS space in 2025 to likewise evolve its IBS platform.[79,80,53]

Other strategies

Staged development and evidence generation

As funding and reimbursement pathways evolve, the potential return on investment for various product types will shift over time. For this reason, it is important to consider the time horizon for solutions of various types to become scalable and economically sustainable at the outset of product development. New product developers have often gravitated initially toward business models with clearer commercial prospects and lower regulatory barriers — launching solutions exempt from regulatory approval initially — such as consumer digital health apps or clinical therapy tools (i.e. DTC and DTP models) — and then evolved them for submission as regulated or branded products. Others have initially built wellness products and other types exempt from premarket notification within in digital care…and sometimes made them available to consumers via subscription models. This staged approach helps developers obtain revenue earlier in their lifecycle while refining their products and sustainably generate data over time (see Callout, Staged Commercial Development and Evidence Generation).

"We saw an opportunity to combine a strong, scientifically sound app with our many years of experience in the field of gastroenterology, and in this way to create added value for patients. We will work to make sure that this digital health application becomes even more user-friendly and instructive through training sessions, test accounts, videos and dialogs with Bayer's field force." [78]

— Tobias Boldt, Cluster Head Germany & Austria Consumer Health, Bayer Vital

"The acquisition of key Mahana Therapeutics assets secures our position as the leader in digital GI care." [53] *"This acquisition includes Mahana's non-FDA-cleared digital IBS assets; the 2.0 version of their CBT-based content, brand, and related materials. We'll be looking at how to bring this into Nerva to improve access to effective brain-gut therapies, especially for patients who can't see a GI psychologist or are stuck on long waitlists."* [81]

— Alex Naoumidis, Co-Founder & CEO at Mindset Health

STAGED COMMERCIAL DEVELOPMENT AND EVIDENCE GENERATION

For developers aiming to gain regulatory approval for a digital therapeutic (DTx), the high cost of clinical studies often leads them to pursue staged product development strategies that support sustainable evidence generation. Many now begin their nascent product's commercial journey by initially creating other product types that are exempt from regulatory approval or fall under enforcement discretion with the aim to evolve them over time. Pursuing these early revenue opportunities can help build evidence to support eventual approval and yield some profit before investing in further clinical studies. These larval stages include consumer digital health products and those for clinical use by providers:

- **Starting with direct-to-consumer (DTC) app or non-digital therapeutic (NDT)**.
  Pursuing a direct-to-consumer model initially may enable digital health products to enter the market quickly with an app and to begin gaining revenue. Data collected can help build and iterate the product, enabling developers to improve an app's user interface and the ability of its modules to engage patients, and can provide early evidence of effectiveness and sustained behavior change. Developers additionally gain the benefit of building a user base and brand recognition in the market while also gaining real-life experience integrating into care or patient life.

- **Starting with digital care for patients or employers**.
  Like the pathway above, this route allows companies to build real-world evidence showing the benefits of self-guided NDT or wellness app in a care setting while iterating their product and gaining market recognition and revenue. For example, Feel Therapeutics, which offers digital mental health care notes reports it has submitted its digital therapeutics for MDD and anxiety for regulatory approval.[82] Similarly, Dynamicare Health — currently operating as a digital care provider to treat substance using its platform technologies — has received breakthrough designation for at least one of its digital therapeutics under development for perinatal smoking cessation and has partnered with health plans and employer benefit programs.[83] By serving as digital care providers companies also get around some commercialization and physician adoption barriers to demonstrate value within care settings. Most companies pursuing this route will likely continue to offer digital care beyond approval, as MamaLift has done with MamaLift Plus.[8,10]

- **Starting with clinically validated tools for HCPs**.
  Some companies have begun their product's journey as tools designed for provider's to purchase and use within clinician-monitored programs, like clinical therapy or remote monitoring tools.
  For instance, Floreo's VR-based care tools for neurodivergent learners are already in use by educators and clinicians and supported by Medicaid waivers in several states while Floreo is pursuing full approval for pediatric autism.[110]

- **Offering tiered access to therapeutic apps**.
  Some developers offer consumer versions of therapeutic apps and then offer a PRO version with enhanced functionality unlocked if their HCP or digital care provider participates. Similar to the digital care scenario, this model may enable modules to be improved while regulatory approvals are underway.

Evolution of regulatory and reimbursement pathways

+ **National approaches to reimbursing or funding digital health technologies have matured as dedicated reimbursement pathways for digital solutions have been developed, assessment frameworks have been formalized, and the number of digital solutions leveraging those pathways has grown.**
+ **New accelerated pathways speed market entry and expand reimbursement to additional digital health product types — including the UK's EVA guidance, France's PECAN pathway for digital therapeutics and telemonitoring tools, Germany's DiPA for long-term care nursing apps, among others.**
+ **Key elements of these policies for innovative technologies are beginning to align globally, with countries taking a staged lifecycle approach to evidence requirements, offering accelerated reimbursement, supporting high-quality evidence generation and aiding their integration into care.**
+ **Each national pathway has its own distinct strengths, with UK's NICE Guidance covering the broadest scope of digital health applications and types; pathways in Germany, France and Belgium providing national funding; billing codes in the U.S. facilitating reimbursement within care; and Digizo.nu in the Netherlands supporting scale up.**
+ **Many of these pathways span digital health solutions that allow healthcare professionals to diagnose, treat and monitor patients remotely — including the Integrated Review and Assessment System (IRAS) pathway in Korea and Belgium's mHealth Pyramid reimbursement pathway.**
+ **Over 300 active billing codes in the U.S. support the use of software-based and mobile health solutions, including 117 codes for software technologies — 77 for AI-enabled tests, 27 for digital therapeutics, and 10 for digital care programs — along with at least 47 codes related to telehealth and 57 to remote monitoring.**
+ **To date, Belgium and France's digital health pathways have only reimbursed telemonitoring solutions: Belgium's mHealth Pyramid accepted eight apps for heart failure, France's PECAN reimburses three for cancer and post-rehab back pain, and devices from nearly 30 companies are now reimbursed via LATM across five chronic diseases.**
+ **Several countries, including the UK, Belgium, and the Netherlands, assess mature digital health use cases using technology assessments and then recommend and/or reimburse multiple products in the category.**

NEW DEVELOPMENTS

Over the past few years, significant policy changes have affected the funding and reimbursement of digital health solutions globally. As policymakers increasingly recognize the ability of digital health technologies to address unmet patient needs, improve outcomes, and close care gaps, they have aimed to accelerate the use of effective digital solutions in care settings.

Following in the footsteps of Germany's Digitale Gesundheitsanwendungen (DiGA) pathway — created in 2019 to accelerate review of patient-facing digital health apps — many other countries have formalized their own national assessment and reimbursement pathways for digital health technologies. Over the past few years, other important policy changes have also affected technology assessment and reimbursement (Exhibit 7).

Though national approaches vary across countries, many national pathways offer accelerated market entry and/or early temporary reimbursement to sustain developers, support high-quality evidence generation, and in some cases, help integrate digital health technologies into care. As a result, new opportunities have become available to digital health products of increasingly diverse types and applications.

Exhibit 7: Recent developments in digital health solution reimbursement 2022–2025

UNITED STATES

May 2022: Digital Health Assessment Framework (DHAF) launched in May by American College of Physicians (ACP) and American Telemedicine Association (ATA) and ORCHA

Aug 2022: Introduction of Remote physiologic and therapeutic monitoring CPT codes (RPM/RTM) by AMA and First HCPCS code to reimburse DTx for mental and behavioral health by CMS

Sep 2022: Major payers publish DTx coverage decisions with mostly negative decisions (Aetna, Anthem, Premera) but select commercial insurances like Highmark and state Medicaid (e.g., Florida) reimbursing

Oct 2022: Access to Prescription Digital Theraputics Act of 2023 first introduced (not yet passed) to create a benefit category for SaMD under Medicare and Medicaid to reimburse PDTs

Jun 2023: Huma receives FDA clearance for its multi-condition disease management platform.

Oct 2023: Highmark covers diagnostic aid Canvas Dx

Sep 2023: AMA study indicates Medicare plans cover all (n=21) digital medicine services via billing codes yet private Medicare Advantage plans do not

In 2024, coverage policies exist for 16 commercial health insurers but most consider them experimental and uncovered

Aug 2024: CMS proposed new HCPCS codes for wearable health devices, including continuous glucose monitors, smartwatches with health tracking capabilities, and wearable ECG monitors

Jan 2025: CMS introduces 3 new HCPCS codes for digital mental health treatment devices, including codes for physician time spent managing these devices

May 2025: Access to Prescription Digital Therapeutics Act reintroduced to Congress

UNITED KINGDOM

Aug 2022: Updates to NICE Evidence standards framework (ESF) include artificial intelligence (AI) and data-driven technologies with adaptive algorithms

Jun 2022 Launch of NICE Early Value Assessments (EVA) that make early recommendations on use of digital health solutions while evidence is generated

2023–2025: Multiple EVAs issued recommending digital health solutions of various types

Nov 2023: Funding announced for 'Talking Therapies using digital solutions' to treat mild to moderate depression

Jul 2024: Updated post market surveillance requirements for Medical Devices in effect

Jul 2025: New HealthTech pathway announced for devices, diagnostics and digital products and 10 Year Health Plan for England announces Apr 2026 revision to include mandated national NHS funding for some cost effective+affordable HealthTech & HealthStore

GERMANY

2022: Updated pricing model for DiGA, capping prices by therapeutic area

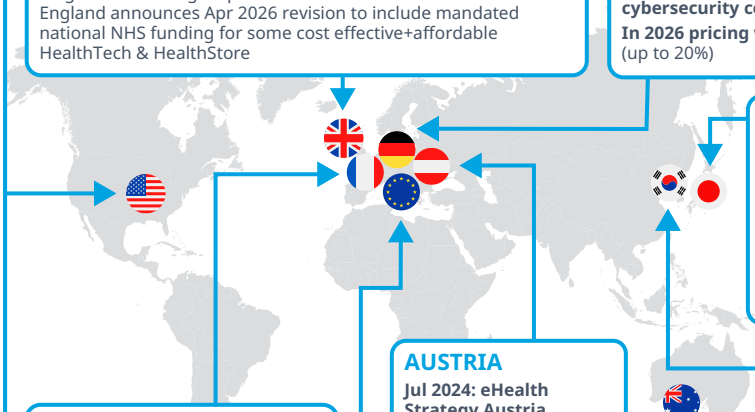
Oct 2022: DiPA pathway created for use of digital nursing applications in home-care and long term care settings

Feb 2024 DigiG act expands DiGA program to include higher-risk Class IIb solutions without provisional listing, and **mandates e-prescription, prospective comparative studies for permanent listing**

Jan 2025 Improved DiGA interoperability with health system required including authentication by GesundheitID and interoperability with German electronic patient health record (ePA)

Jan 2025 DiGA providers must obtain increased cybersecurity certification according to BSI TR-03161

In 2026 pricing will be partially performance-based (up to 20%)



JAPAN

2022: Insurance coverage issued for CureApp hypertension DTx

2024: DASH for SaMD2 takes effect with two-stage pathway, early conditional reimbursement, 6-month review for innovative SaMD and DTx

2024: DHS eligible for new financial incentives/NHI price premiums

AUSTRIA

Jul 2024: eHealth Strategy Austria

2025: Austrian DiGA pilots on 5 German DiGA for chronic disease

2026: Expected creation of a DTx reimbursement pathway

KOREA

Oct 2022 IRAS accelerated pathway created, offers temporary reimbursement for innovative medical devices, DTx

2023: First two DTx approved via IRAS & granted temporary reimbursement after ~8–10 months

Jun 2023 MFDS recognizes RWE as clinical trial data for DHS

Aug 2023: New reimbursement listing guidelines set temporary reimbursement rates for IRAS approved technologies, and requires Rx"code" and patient use data to be sent to prescriber (use data also to HIRA)

Jan 2025 Digital Medical Products Act (DMPA) regulatory framework for digital health products

FRANCE

Mar 2023: PECAN fast-track reimbursement pathway created for DTx and RPM tools with DiGA-like reimbursement,

Jun 2023: LATM Pathway created for RPM tools

July 2023: first telemonitoring solution reimbursed via PECAN: Cureety for Cancer

Apr 2024: therapeutic DTx pricing is set under PECAN

AUSTRALIA

National Digital Health Strategy 2023–2028 outlines vision for a data-driven digital health system

Jul 2024: Australian government allocates significant funding to support digital health initiatives, including the Digital Restart Fund and partnerships DH accelerators

Feb 2025: Australian Institute of Digital Health calls for bipartisan policy on digital health

EUROPEAN UNION

Mar 2023: Huma receives world's first multi-condition approval under EU MDR

July 2023: Updates to data transfer guidelines from U.S,/EU data privacy agreement enable DiGA cloud infrastructure in U.S.

Source: IQVIA Institute, Jul 2025.

Software as a Medical device (SaMD). American Medical Association (AMA). United Health Group (UHG). Blue Cross Blue Shield (BCBS). Digital Transformation (DX) Action Strategies for Healthcare (DASH), Ministry of Food and Drug Safety (MFDS); The Ministry of Health, Labour and Welfare (MHLW); Integrated Review and Assessment System (IRAS) pathway, Medical Device Regulation (MDR), Real world evidence (RWE), Centers for Medicare & Medicaid Services (CMS).

Many national pathways now span diagnosis, treatment and monitoring, including mHealthBelgium's mHealth Validation Pyramid for mobile apps, Korea's Integrated Review and Assessment System (IRAS) and the UK's Early Value Assessments (EVA).[84] Although most products initially approved via the DiGA pathway are digital therapies, apps that help recognize, monitor, or treat/alleviate disease or injury are also eligible.

Digital telemonitoring/RPM solutions that use sensor-based devices, wearables and ePRO apps to remotely assess or track patient health have been a focus of recent approvals under several new pathways. These solutions help improve the ability of providers to detect new health issues and exacerbations, remotely monitor and manage a patient's condition and enable timely intervention that may help reduce hospital admissions, improve health outcomes and potentially lower costs.[1]

For instance, France's Liste des activités de télésurveillance médicale (LATM)[85] pathway was created specifically for remote monitoring devices that transmit data about a patient's health to a medical professional or team, and both RPM and digital therapeutics tools are eligible under France's PECAN pathway (Prise en charge anticipée), which launched in November 2022.[86] Digital solutions for remote patient monitoring were also the first to gain permanent approval under PECAN and Belgium's pathway in 2025. In the U.S., an American Medical Association (AMA) study in 2023 found that most commercial payers covered remote physiologic monitoring, and our recent analysis of medical claims data suggests that Medicare now does also (see Reimbursement and uptake in the United States).[87]

Dedicated reimbursement pathways for other types of digital tools have also emerged, such as Germany's Digitale Pflegeanwendungen (DiPA) pathway, established in 2022 for patients in home-care and long-term care settings. These patient- and caregiver-facing "nursing" apps aim to reduce impairments, prevent health deterioration to avoid escalating care needs, and support independence and self-care. However, as of October 2025, no apps were listed, and at least one solution from Lindera was rejected — an AI-powered mobile application designed to assess mobility and fall risk in older adults and provide personalized exercise recommendations to maintain independence and prevent falls.[88]

MATURITY OF NATIONAL PATHWAYS

Over the past few years, national approaches to the funding and reimbursement of digital health solutions have matured across key markets. Reimbursement and funding pathways developed specifically for digital health technologies have emerged, guidance on their assessment has been formalized, and the number and types of digital solutions reviewed and approved through those pathways has grown. Different levels of digital health maturity can be identified across markets based on the existence of such formal pathways and frameworks and how actively they are used to review products (Exhibit 8).

Exhibit 8: Maturity level of digital health reimbursement pathways by country

Lower → Higher

SPAIN	ITALY	BRAZIL	AUSTRALIA	JAPAN	SOUTH KOREA	BELGIUM	UNITED KINGDOM	UNITED STATES	FRANCE	GERMANY
AETSA	AGENAS	CONITEC	MSAC / MBS	MHLW / Chuikyo	MFDS, NECA-nHTA IRAS Pathway	INAMI-RIZIV mHealth Belgium	NICE HealthTech, ICBs, NHS England, DHSC	CMS (Medicare & Medicaid), State Medicaid, VA FSS, MCOs IDNs, employers	HAS/CNEDiMTS, PECAN, LATM, LPPR, Hospital purchasing groups	BfARM, GKV-SV (DiGA, DiPA), Krankenkassen
Less mature, no assessment framework.		Less mature.	Less mature, no assessment framework.	Less mature, no assessment framework.	More mature, Established assessment framework.	Established framework, beginning to offer national public reimbursement.	Heterogeneous with multiple routes; National guidelines and local decisions.	Mature, fragmented; heterogenous payer assessment frameworks.	Maturing and becoming more centralized, with national public reimbursement.	Well-established and mature framework for national public reimbursement.
Spain and Italy lack dedicated frameworks. There are few examples in Spain of DHS assessment and reimbursement, and decisions in both Spain and Italy have been ad-hoc at the subnational level.		Brazil approved its first DTx in 2023. In 2020 Brazil laid out an 8-year Digital health strategy and action plan to promote innovation and establish mechanisms to monitor and evaluate key collaborations and digital health trends.	Australia currently lacks a formal national pathway, but some DHS have been reimbursed ad hoc by Dept. of Health and Aged Care. DHS may also be able to access state-level and private insurer funding, and support from the Digital Restart Fund.	Japan has no DHS-specific framework, but since 2024 offers two-stage priority review pathway with early conditional reimbursement. Decisions are made at the national-level 4-7 months after approval. Pricing premiums are offered for early market entry and innovation.	Korea's IRAS pathway provides accelerated approval and temporary reimbursement. Two of six approved DTx have opted-in to public temporary reimbursement, but low rates and high patient cost responsibility have kept DHS use low overall.	Belgium's Mhealth validation pyramid assessment framework was finalized in 2021 and newly granted reimbursement to 8 telemonitoring/ RPM apps for heart failure in Jan 2025. Payments for developers and providers are bundled and set by the specific care pathway.	Since NICE in the UK recommended its first DTx (Sleepio) for NHS use in 2022 it has issued 20+ Early Value Assessments (EVA) conditionally recommending DHS. Its new HealthTech programme launched in July 2025 takes a lifecycle approach where early stage DHS can gain conditional recommendation.	The U.S. has multiple funding and reimbursement pathways for DHS, including via select commercial insurances with distinct assessment frameworks, employers, Medicare, and State Medicaid. The creation of billing codes has helped to facilitate payment to HCPs and device companies for DHS, virtual and remote care.	France's PECAN fast-track pathway for DTx and telemonitoring (RPM) solutions launched in November 2022, with DiGA-like reimbursement. three RPM devices gained reimbursement via PECAN and devices from 29 companies are now reimbursed via its LATM pathway. Pricing guidance was published in April 2024.	Germany has a structured approach and guidance for DHS review and reimbursement. Apps on the DiGA directory must be reimbursed by all Gesetzliche Krankenversicherung (sick funds). The DigiG law now allows for Class IIb devices to be approved and sets the expectation for e-prescription of DiGA .
Reports suggest Italy is considering centralized reimbursement, while Spain's will likely be ad-hoc in some regions.		Future may see movement towards this vision and more approvals.	Within the next 2-3 years pathways are expected to be revised and become fit for purpose.	Future may see standardized regulations geared towards digitization and reimbursement.	Likely some DTx approvals in the future with limited reimbursement potential.	Belgium has announced it will continue to conduct HTAs in high priority areas and add care processes to reimburse DHS.	Centralized funding for some NICE-recommended HealthTech products and a HealthStore site to list centrally-procured & well evidenced apps/ DTx expected mid-2026.	Future will likely see expanded coverage among Medicare and other payers for DTx and AI-enabled tests used within clinical care.	Future will likely see more approvals under PECAN and this will become a more established pathway.	Future will see electronic DiGA prescription in 2026, and likely the listing of higher risk class products and the first DiPA nursing app.

Source: IQVIA Institute, Jul 2025.

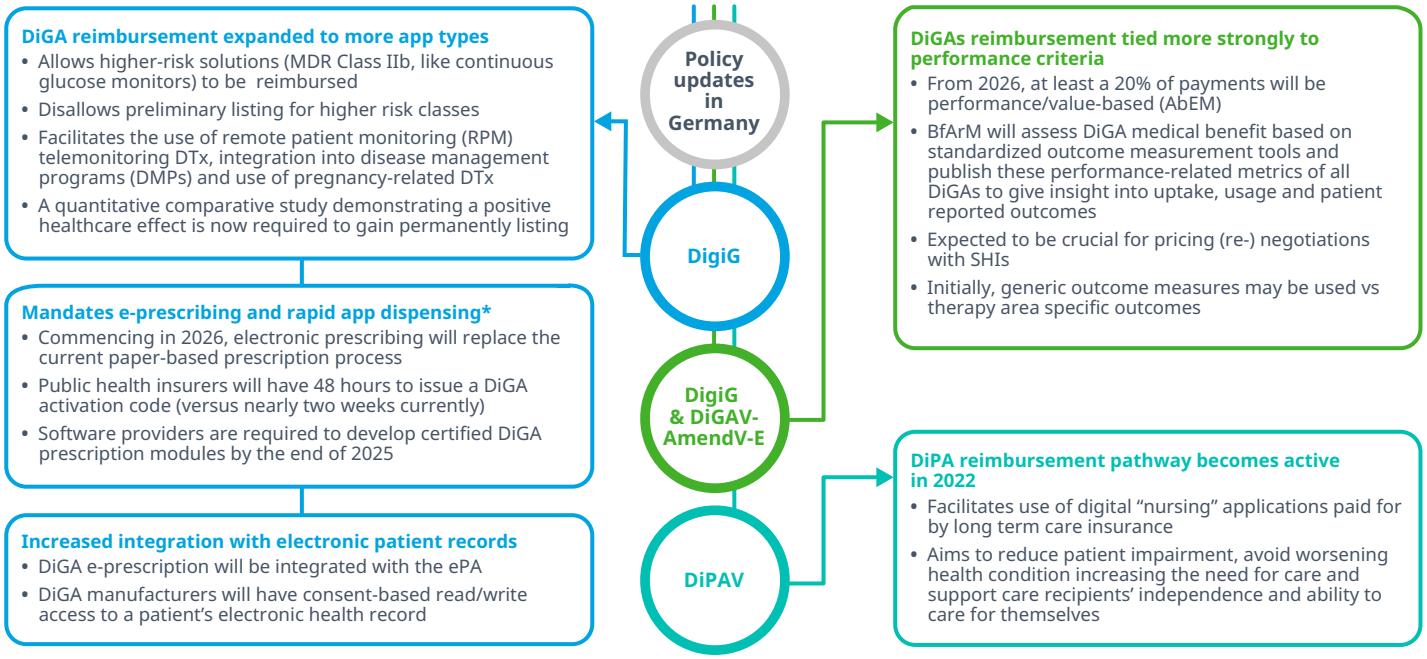
Notes: Digital health solutions (DHS). Software as a medical device (SaMD). Digital therapeutic (DTx). remote patient monitoring (RPM). Andalusian Health Technology Assessment (AETSA). The Agency for Regional Healthcare (AGENAS). National Committee for Technology Incorporation (CONITEC). Ministry of Food and Drug Safety (MFDS). National Evidence based Healthcare Professional Collaborating Agency (NECA). New Medical Technology Evaluation Committee (nHTA). Ministry of Health, Integrated Review and Assessment System (IRAS) pathway. Labour and Welfare (MHLW). Central Social Insurance Medical Council (Chuikyo). National Institute for Health and Disability Insurance (INAMI-RIZIV). National Institute for Health and Care Excellence (NICE). Department of Health and Social Care (DHSC). Medical Technologies Guidance (MTG). Centers for Medicare & Medicaid Services (CMS). Managed care organizations (MCOs). VA Federal Supply Schedule Service (VA FSS). La Prise en Charge Anticipée Numérique (PECAN). Liste des produits et prestations remboursables (LPPR). Liste des activités de télésurveillance médicale (LATM). The Federal Institute for Drugs and Medical Devices (BfArM). Digital health applications (DiGA). Digital nursing applications (DiPA). La Commission Nationale D'évaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDiMTS). Krankenkassen are public health insurance companies in Germany.

Germany

Since approving its first digital therapeutic in September 2021, Germany has remained most mature market for digital health solutions, offering revenue opportunities and access to its national marketplace through the well-described DiGA pathway which takes a systematic approach to national assessment, reimbursement and pricing.[89] Many solutions have applied for and received national reimbursement, making Germany a first key market that developers seek to commercialize in. The DiGA pathway allows manufacturers of patient-facing mobile apps to receive preliminary listing and reimbursement for up to one year if they show early evidence of patient-relevant medical benefits — such as improved health, survival, quality of life, or disease duration — or care improvements for patients or caregivers.[90,91] This initial listing period is designed to support evidence generation to prove a product's medical benefit — in which case the DiGA is permanently listed and reimbursed — or a product can be de-listed if it fails to reach target evidence criteria. In some cases it can receive an extension to the preliminary listing period.

As of July 2025, Germany's DiGA pathway listed 69 solutions since its inception (of which 13 had been eliminated from the directory) and of the 56 current listings, nearly 80% (n=44) had been permanently recorded and the remaining twelve were provisionally listed.[92] While the initial DiGA approvals focused on digital therapeutic apps, a recent law, the Digitalisierungsgesetz (or DigiG) which came into effect in March 2025, expanded the DiGA program to include a wider range of medical devices including Class IIb risk level devices, thereby aiding future approvals of remote patient monitoring solutions. It also lifted the 30% cap on provider time billed for telemedicine, facilitating broader digital care delivery and accelerated app dispensing to patients (Exhibit 9).[93] Separately, a draft bill from January 2025 — the Second Ordinance Amending DiGAV (DiGAV-AmendV-E — also proposed a shift to a partial value-based payment system (AbEM) linked to usage metrics and patient-reported outcomes.[94]

Exhibit 9: Recent policy implications for DiGA and DiPA in Germany, 2022–2025



Source: IQVIA Institute, Jun 2025; Various government policy sources: Second Ordinance Amending DIGAV (DiGAV-AmendV-E), 'Digitalisierungsgesetz' (DigiG); Digitale Pflegeanwendungen-Verordnung (DiPAV).

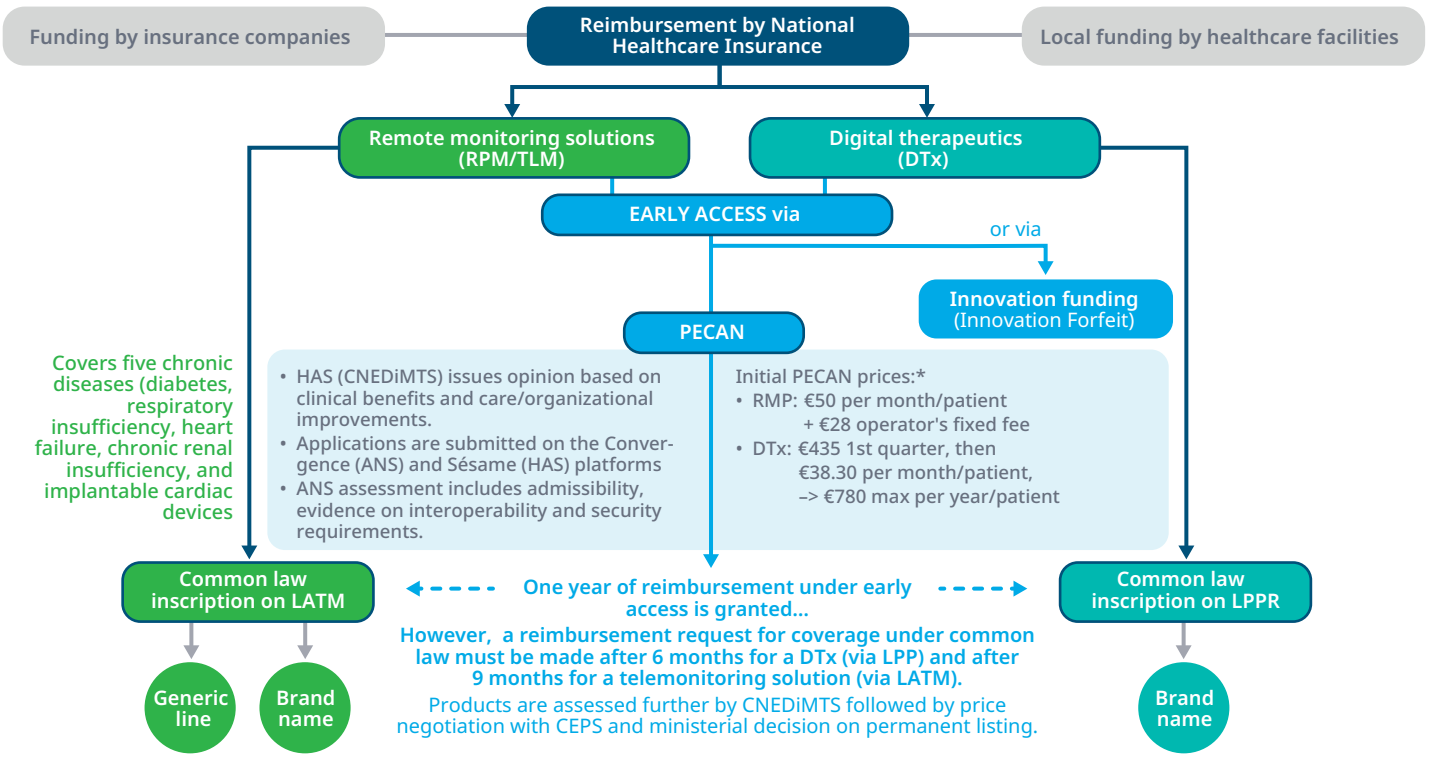
Notes: *Currently few patients use the separate mobile app enabling ePrescribing. Future integration of e-prescription data with the ePA is not expected to be mandatory before January 2026, so impact may be slow. ABEM - Anwendungsbegleitende Erfolgsmessung", Accompanying Success Measurement.

France

With its creation of multiple new national reimbursement pathways, France's approach to digital health has matured, placing it next after Germany. Its new PECAN 'fast-track' pathway, launched in March 2023, enables manufacturers of digital therapeutics and remote patient monitoring solutions to secure DiGA-like temporary reimbursement while they finalize confirmatory clinical trials. Its LATM pathway (Liste des activités de télésurveillance médicale), introduced in June 2023, provides common law reimbursement for telemonitoring solutions targeting chronic diseases, and grew out of the ETAPES pilot program that ran from 2018 to 2022 (Exhibit 10). Still, in comparison to Germany's DiGA, fewer solutions have been appraised and approved so far via PECAN and the pathway lacks formalized evidence requirements and assess solutions case-by-case.[95]

With PECAN's launch, digital health developers with sufficiently mature technologies now have a dedicated route to early market access in France. Although the highly selective Innovation Forfait pathway also provides early-stage funding to support initial clinical use — often in the context of pilot studies or evaluations — it is open to innovative medical devices and diagnostics beyond digital health tools. Inspired by Germany's DiGA pathway, PECAN allows manufacturers of digital therapeutics and telemonitoring (RPM) products demonstrating medical benefit to obtain temporary reimbursement for a year. It also enables the product to gain early use care settings as they approach pivotal study completion and may thereby help developers gather real-world data from studies that include the French population.

Exhibit 10: Overview of the PECAN reimbursement pathway for digital medical devices in France



Source: IQVIA Institute, Jul 2025. IQVIA Consulting.

Notes: *This amount will decline over time based on the number of "average monthly active file" of patients monitored remotely for the same indication using any product included in PECAN or LATM. TLM – Télésurveillance Médicale. Prise en charge anticipée numérique (PECAN), Haute Autorité de Santé (HAS); Agence du Numérique en Santé (ANS); Liste des Produits et Prestations Remboursables (LPPR); Liste des Activités de Télésurveillance Médicale (LATM), Comité Économique des Produits de Santé (CEPS).

Exhibit 11: Digital solutions assessed in France under PECAN

Medical device	Agency and opinion	Company	Therapy area	Type	Date of opinion
AXOMOVE THERAPY	HAS PECAN: Positive	Axomove	Back pain	Remote Care and Monitoring Solution	12/26/2024
CONTINUUM + CONNECT	HAS PECAN: Positive	CONTINNUM +	Oncology	Remote Monitoring Solution	06/09/2024
CUREETY TECHCARE	HAS PECAN: Positive, now LATM	CURRETY	Oncology	Remote Monitoring Solution	07/25/2023
KRANUS EDERA	HAS PECAN: Negative	KRANUS HEALTH	Erectile Dysfunction	Digital Therapeutic	03/24/2025
OTO	HAS PECAN: Negative	OTO HEALTH	Tinnitus	Digital Therapeutic	03/18/2025
THERAPIE DIGITALE JOE	HAS PECAN: Negative	LUDOCARE	Pediatric asthma	Digital Therapeutic	27/01/2025
HELLOBETTER Insomnie	HAS PECAN: Negative	GET.ON	Chronic Insomnia	Digital Therapeutic	07/23/2024
TUCKY CENTER	HAS PECAN: Negative	e-Takes Care	Oncology /Obesity / Cardiology	Remote Monitoring Platform	10/17/2023
PRESAGE CARE	HAS PECAN: Negative	PRESAGE	Chronic diseases	Remote Monitoring Solution	07/11/2023

Source: IQVIA, Jun 2025; Haute Autorité de Santé (HAS) Avis d'évaluations de la CNEDiMTS (PECAN).
Notes: La Prise en Charge Anticipée Numérique (PECAN). None approved have been purely dispositifs médicaux numériques à visée thérapeutique.

However, manufacturers must be close to finalizing confirmatory evidence when applying to PECAN, as an application for permanent registration is required shortly after temporary reimbursement is issued. Digital therapeutics must submit confirmatory evidence to be included on the LPPR list of reimbursed products and services, within six months of receiving early reimbursement, while telemonitoring solutions seeking inclusion on LATM must do so within nine months. If approved, reimbursement is granted for several years following price negotiations.

A remarkable aspect of PECAN is that it is open to all risk classes of devices (I, IIa, IIb, III), and therefore potentially covers a broader set of software-based devices than DiGA, which was recently expanded to include Class IIb. This underscores PECAN's intended central role for digital innovation, and in theory creates reimbursement opportunities for higher-risk solutions, such as multi-condition disease management SaMD, which can be Class IIb.

France has also expanded the number of digital solutions reimbursed via its two pathways.[96] As of June 2025, three remote monitoring solutions for cancer and low back pain had been made available via PECAN, among the seven or more evaluated (Exhibit 11). Additionally, telemonitoring devices from more than 29 manufacturers gained reimbursement across six application areas, some using generic line reimbursement rates (Exhibit 33).[97]

Obtaining approval via PECAN has proven challenging however and CNEDiMTS cited several recurring issues among solutions received negative opinions.[98–102] These included:

- **Confirmatory studies were not aligned with PECAN's timelines** for subsequent LPPR submission within 6–9 months: *("the ongoing study will not provide sufficient data for CNEDIMTS to issue a subsequent opinion on the request for coverage under the LPPR within the allotted time.")*

- **Insufficient evidence of clinical benefit or care innovation**: Applicants failed to show that adoption by care organizations would yield clinical benefits or improve care delivery without compromising quality *(access to care, quality of management, or organization of care). ("data does not support the presumption of innovation, either clinical or organizational")* or *("does not confirm the presumption of organizational innovation…within the care pathway compared to conventional management.")*
- **Reliance on product-non-specific or outdated evidence**: Some dossiers presented studies that were not specific to the product under review or were based on earlier device versions, arguing technical equivalence rather than providing direct evidence. *("The applicant's argument is based on non-specific data and a claim of technical equivalence to earlier generations… which have been the subject of clinical studies.")*
- **Unclear patient adherence or usability data**: *"Evidence on patient engagement and adherence is insufficient to confirm real-world feasibility."*

Finally, the fact that France grants centralized national reimbursement positions it ahead of the United States and United Kingdom, where a greater number of digital health solutions are reimbursed but coverage remains fragmented and largely ad hoc. However, the UK is expected to introduce a formal HealthTech funding pathway for digital solutions by 2026, which could allow it to surpass France in terms of maturity.

United States

The United States is considered a mature market based on the number of digital health solutions that have applied for and received reimbursement and the fact that payers have developed assessment frameworks, however, reimbursement currently remains decentralized. Due to the fragmented insurance landscape — where multiple payers coexist and employer-sponsored insurance also plays a role — achieving broad national coverage remains a challenge. As a result, multiple pathways exist for securing coverage or payment, and opportunities vary by both product type and payer type.

Reimbursement may be obtained from commercial or private payers (~65% of covered lives), which manage plans sold to employers and individuals, and from public payers like Medicare and Medicaid (~36% of lives).[104] Some companies have also made inroads with State Medicaid agencies, the U.S. Department of Veterans Affairs (VA), and other federal care providers to secure coverage through direct contracts and may then be included on their preferred drug lists and formularies. Around 8% of U.S. patients are covered under federal programs such as TRICARE, CHAMPVA, or VA benefits, and another 8% remain uninsured.[105] Similar to the NHS in the UK, the VA has played a key role by piloting and reimbursing select digital therapies and lists contracted solutions with negotiated pricing on the Federal Supply Schedule.

On the commercial side, while leading payers still consider the majority of digital health solutions investigational, and have not issued broad coverage, most now cover and reimburse for one or more well-evidenced digital health solutions. This has positioned self-insured employers — who offer digital tools as wellness benefits to improve employee productivity and reduce health-related costs — as critical sources of funding. To serve this market, payers and pharmacy benefit managers (PBMs) offer upgraded plans with digital formularies on an opt-in basis to employers. And, beyond payer reimbursement, manufacturers may also offer solutions directly to providers, health systems, and consumers.

However, the lack of formal, published reimbursement frameworks continues to limit broader access. Coverage decisions are made on a product-by-product basis — with commercial and public payers applying different evaluation approaches using their own assessment frameworks — making it challenging for digital developers to anticipate evidence

requirements and optimize their evidence generation plans accordingly.

Still, the highly fragmented U.S. market has proven to be extremely dynamic. By 2024, the FDA approved hundreds of digital health tools, including 46 prescription digital therapeutics (DTx) and 120+ mobile digital diagnostics for health assessment (among the 1,033 distinct AI-enabled medical devices approved through May 2025).[1,106] Other non-prescription digital solutions are also widely available, including clinical tools used under provider supervision and mobile health apps for self-guided education, self-care, and wellness — many of which are either exempt from premarket notification or subject to FDA enforcement discretion.[1]

In the United States, a key enabler of reimbursement has been the creation of billing codes by CMS (HCPCS codes) and the AMA (CPT codes) relating to digital health (see Billing for Digital Care in the U.S. Callout).

These codes facilitate payment to providers and suppliers and now play a central role in supporting integration into care. Based on an IQVIA Institute analysis, at least 303 active billing codes in the U.S. facilitate the use of software-based and mobile health solutions, including 117 codes tied specifically to the use of software-based technologies such as SaMD, SiMD and AI-SaMD (Exhibit 12).

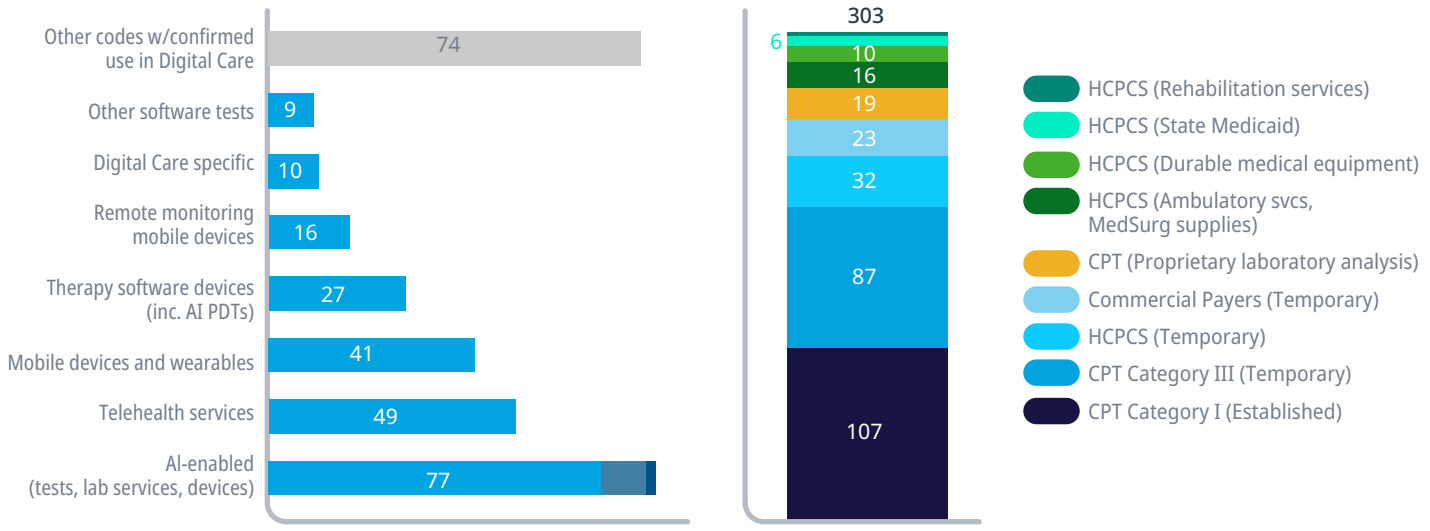
These include, with some overlap: 77 AI-enabled tests for health assessment (several used at the point-of-care), 27 therapeutic mobile devices and an additional 10 codes for digital care. However, only 21 codes reimburse specifically for the supply/setup of software-based devices and digital care programs, most of which are temporary codes describing innovative technologies. An additional 129 codes support wraparound services that enable virtual/digital care: including 47 codes related to telehealth (6 for "online" care and others for communication technology-based services and virtual care delivery), 74 services commonly delivered virtually (and known to be used by digital care providers), and 57 that describe remote care codes for telemonitoring devices and services.

BILLING FOR DIGITAL CARE IN THE U.S.

In the United States, a range of stakeholders have developed billing codes to support reimbursement for digital tools and enable providers to bill for time spent using these technologies in care delivery. These include the American Medical Association's (AMA) Current Procedural Terminology (CPT-4) codes and the Centers for Medicare & Medicaid Services' (CMS) Healthcare Common Procedure Coding System (HCPCS). In some cases, commercial insurers have requested custom billing codes to allow contracted digital solution providers to bill for services.[69]

Providers may use these codes to bill payers for digital tools — including device supply or setup — and for clinical services like onboarding patients, delivering care through digital programs, or interpreting data collected by these solutions. Existing codes now support software-based tools used for remote health assessment, monitoring, and therapy, including digital therapeutics, medication management apps, clinical therapy tools, and AI-enabled diagnostic aids. Some codes also allow non-physician professionals, such as health coaches, to bill for services delivered via digital health solutions.

Exhibit 12: Digital health related billing codes in the United States by use and code type



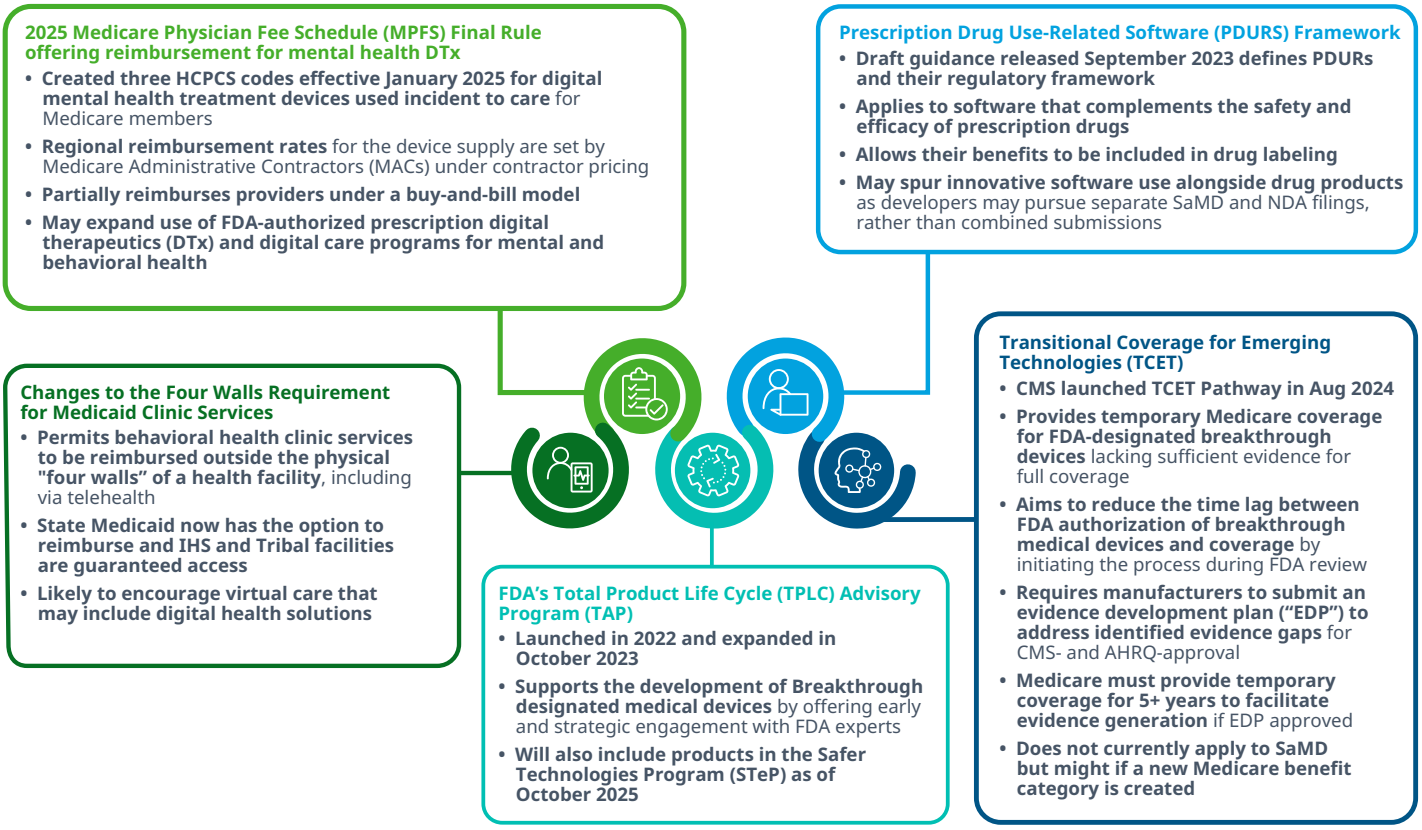
Source: IQVIA Institute Digital Health Billing Code Database; Sep 2025.

This means only select digital tools are directly reimbursed within care, and reimbursement opportunities currently vary significantly based on the type of digital health solution, payer type, therapy area, and care setting (see Section, Reimbursement opportunities in the U.S.). Importantly, the existence of billing codes — especially temporary ones — also do not guarantee reimbursement in the U.S. They simply enable manufacturers to bill insurers if they successfully negotiate contracts with payers, PBMs, or care delivery organizations.

Some recent policy changes have notably opened additional routes to reimbursement (Exhibit 13). CMS' 2025 Medicare Physician Fee Schedule Final Rule created new workarounds for pure SaMD digital therapeutics to be reimbursed "incident to" care. These products had previously been ineligible for reimbursement as durable medical equipment due to the lack of custom hardware. Specifically, in January 2025, prescription digital mental health treatment devices were made "coverage allowable" under new contractor-priced G-codes. However, prices were not set at the product level and are determined regionally by Medicare Administrative Contractors (MACs). The result is that Medicare may only partially reimburse providers for supplying digital tools under a buy-and-bill model. Other new codes facilitate the use of digital health solutions by covering virtual care from non-providers (like health coaches, dietitians, etc.) incident to a qualified provider's care.

Finally, while the U.S. does not have a formal accelerated regulatory pathway specifically for digital health technologies, the FDA has taken steps to streamline product development, regulatory review and adoption of innovative technologies through targeted guidance and pilot programs. For life sciences companies, FDA's draft guidance on Prescription Drug Use-Related Software (PDURS),[107] issued in September 2023, made it easier for biopharma manufacturers to launch software adjuncts to traditional therapeutics by filing supplemental NDAs rather than full NDAs — reducing regulatory risk. And the Total Product Life Cycle (TPLC) Advisory Program (TAP), introduced in 2023, plays a parallel role to concierge services in other countries by expediting market access for innovative devices,

Exhibit 13: Recent U.S. policies relating to digital health solutions



Source: IQVIA Institute, Oct 2025.

including those with Breakthrough Device designation or improved safety profiles under the Safer Technologies Program (STeP).

For TAP-accepted devices — such as Floreo VR for autism, which qualified for both Breakthrough and TAP programs — the FDA provides early engagement and support before pivotal trials, helping ensure study designs meet regulatory expectations.[108] TAP also facilitates dialogue with commercial stakeholders to address market adoption, clinical integration, and patient access. Finally, the Innovative Science and Technology Approaches for New Drugs (ISTAND) program has become a permanent pathway to qualify novel drug development tools (DDTs), including those based on AI or digital health, such as digital biomarkers.[109]

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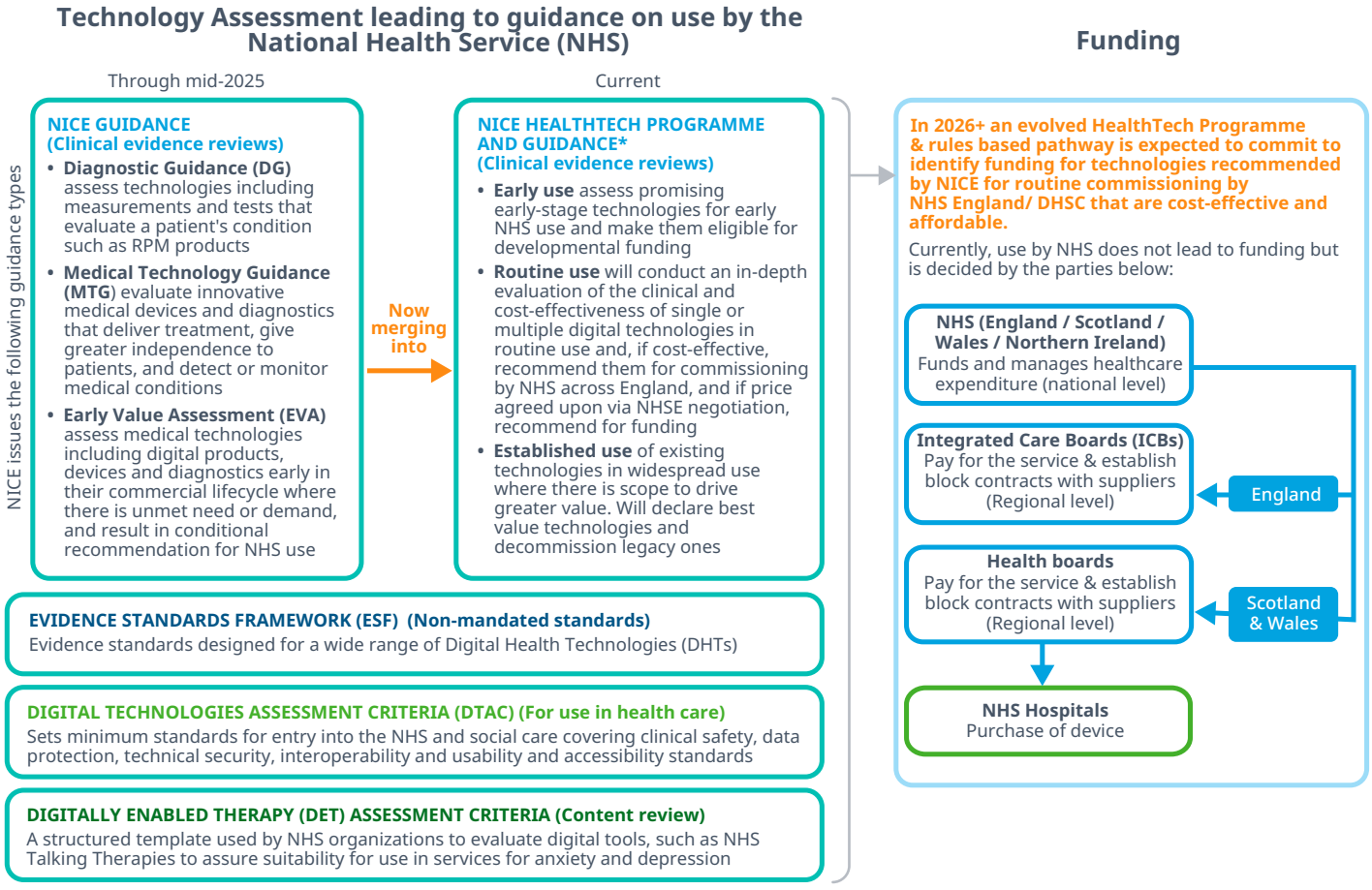
United Kingdom

In recent years, the UK's National Institute for Health and Care Excellence (NICE) has consolidated assessment of digital health solutions at the national level and, together with the NHS, has taken steps to integrate promising technologies into established care paradigms. As a result, the UK now has a rigorous national-level assessment system to review the clinical evidence, technology, and content of digital health technologies and issue guidance on their use by NHS England; however, reimbursement currently remains decentralized.

Assessment criteria include NICE's Evidence Standards Framework (ESF), which guides digital health developers on the types of evidence required; NHS Digital Technology Assessment Criteria (DTAC, February 2021), which governs technological and quality requirements for use in health and social care; and the Digitally Enabled Therapy Assessment Criteria (DET, May 2023), which ensures that products intended for use in NHS Talking Therapies align with NICE standard treatment protocols and required clinician training (Exhibit 14).[110]

Exhibit 14: Digital health technology assessment in the United Kingdom



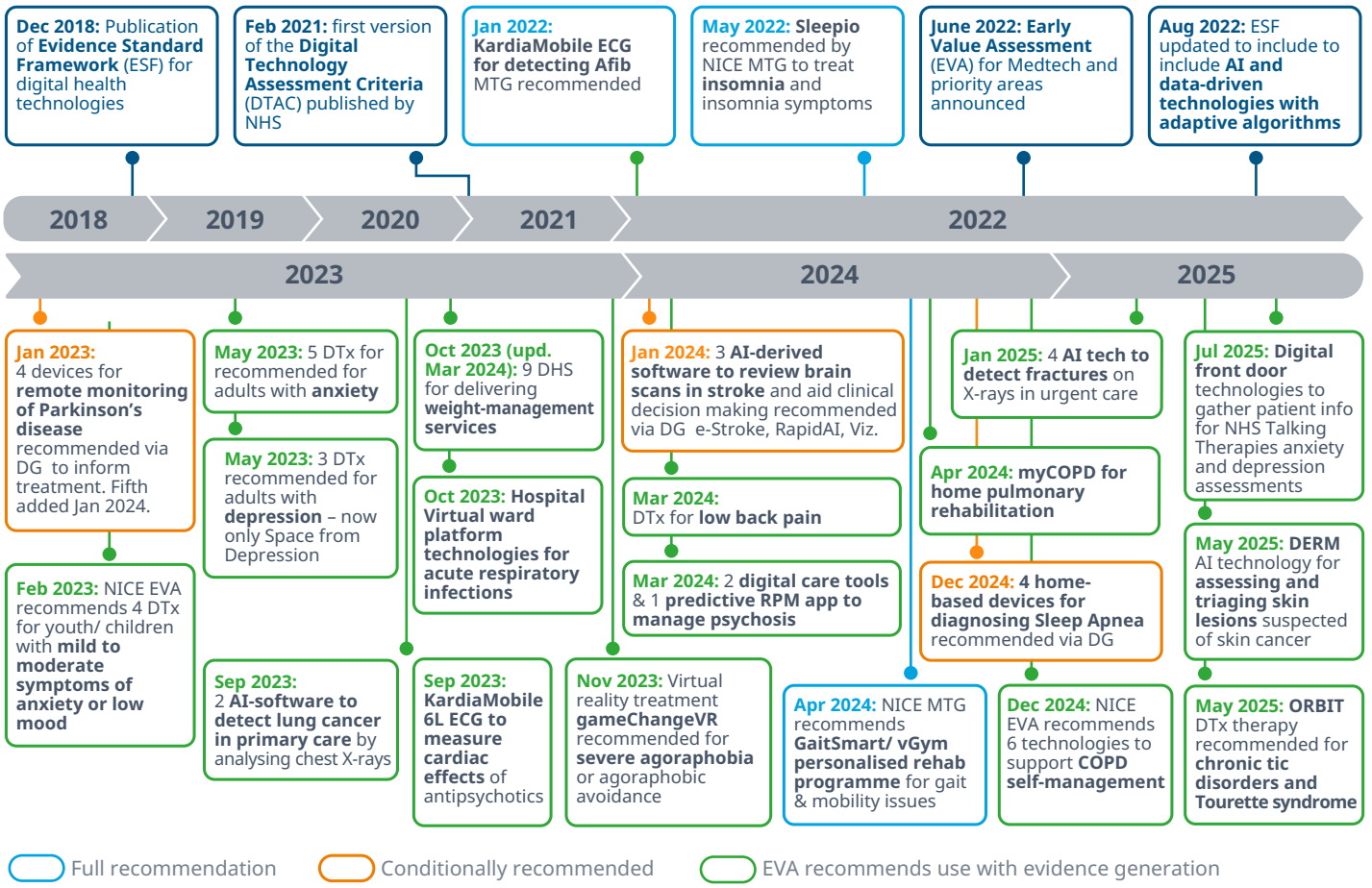
Source: IQVIA market experts; Accelerated Access Collaborative. Health Technology Pathway: Navigation Tool for Innovators in England Published March 2023; NHS England. Building an integrated, rules-based medical technology (medtech) pathway: engagement on proposals [Internet, accessed 2025 Jul 25].

Notes: *The new HealthTech Programme will issue guidance on devices, digital and AI technologies & diagnostics and also absorbs the Interventional Procedures Programme (IPG). Funding comments related to guidance are expected to apply in 2026 onward as the pathway evolves to evaluate, fund, and commission. Department of Health and Social Care (DHSC). NHS England to be replaced by DHSC from 2026 onwards.

NICE then issues recommendations through various guidance formats intended to influence NHS use and regional reimbursement decisions. Until mid-2025, this included Diagnostics Guidance (DG), Medical Technology Guidance (MTG), and Early Value Assessments (EVAs), however, in July 2025, NICE launched the HealthTech Programme, which consolidates assessment of medical devices, diagnostics, and technologies supporting interventional procedures (including AI and digital health) into a single pathway.[111] Rather than focusing on product type, the new HealthTech guidance will be issued based on evidence maturity — whether they have enough evidence to recommend them for "Early Use," "Routine Use," or "Established Use" — which typically links to their stage of development and commercialization.[112,113]

The creation of EVA in June 2022 marked the first step toward this lifecycle model.[114] Similar to PECAN and DiGA in France and Germany, EVA guidance aimed to bring innovative, early-stage technologies addressing national unmet needs into NHS use and support further evidence generation. It provided a route for manufacturers to receive initial recommendations for use "in practice" and has expanded opportunities for digital health developers to gain recognition and commercialize their products in the UK (Exhibit 15).

Exhibit 15: NICE's recommendations on mobile digital health use by the National Health Service (NHS)



Source: IQVIA Institute, Jul 2025. NICE Early Value Assessments (EVAs). Medical Technologies Guidance (MTG). Diagnostics Guidance (DG).

Notes: Includes centralized decisions by NICE pertaining to digital therapeutics, app-linked digital health solutions including digital or blended care programs, digitally enabled therapies (DET) which deliver a substantial portion of therapy online but are designed to be used with therapist assistance, remote monitoring technologies and digital diagnostics. Deep Ensemble for Recognition of Malignancy (DERM). Online Remote Behavioural Intervention for Tics (ORBIT; Mindtech). National Health Service (NHS).

Since February 2023, NICE actively issued at least 20 EVAs in rapid succession recommending over 47 digital solutions for NHS use (and even more for research) — positioning the UK as a leader in using technology assessment to find the right place for various digital solutions within national care.[115] These EVAs have assessed the widest range of digital health solution types of any country — including digital therapeutics, rehabilitation tools, clinical therapy platforms, digital care programs, remote monitoring technologies, virtual wards, and AI-driven radiology and radiotherapy tools.

EVAs have also focused on mature use cases where multiple technologies compete for adoption, enabling NICE to assess evidence across a class and compare effectiveness. This has led to conditional recommendations for multiple solutions (Multi-Tech Guidance), and in some cases multiple products from the same manufacturer, as was the case with SilverCloud.

To receive an EVA recommendation for use in practice, manufacturers must present robust evidence — more stringent than DiGA's preliminary requirements for provisional reimbursement — but still lack sufficient data to support routine NHS use.[116] Further, EVA is a lengthier process than the 12-month timeline seen in France and Germany and does not yet offer automatic temporary funding during evidence generation… although funding support is anticipated in the near future.

When evidence gaps are identified, developers of EVA-recommended solutions are given an opportunity to collaborate with NICE to form an evidence generation plan to fill them over a three-year period with aim to clarify the solution' proper place in care settings, effectiveness in intended patient populations and its cost effectiveness in the context of provider time and resources. This involves partnering with various stakeholders and — once sufficient evidence is generated — NICE may reassess the solution and issue full recommendation for routine NHS use.

Despite NICE's recommendations, the UK currently lacks a national reimbursement pathway with guaranteed or systematic funding, creating barriers for manufacturers. This places the UK's current maturity behind France and Germany, where digital health solutions gain reimbursement following national assessment via PECAN and DiGA. Instead, funding is typically secured ad hoc through regional contracts with Integrated Care Boards (ICBs), which allocate resources from their annual budgets. However, this may soon change, as the recent publication, "Fit for the Future: 10 Year Health Plan for England", announced a plan to assure funded reimbursement beginning in April 2026 for some digital technologies with the new HealthTech pathway (see Global reimbursement opportunities, page 66).[50]

Belgium

After a rocky start, Belgium notably shifted in maturity this year when its mHealthBelgium mHealth Pyramid national reimbursement pathway — finalized by the government in 2021 — made seven mobile applications permanently eligible for financing by the National Institute for Health and Disability Insurance (INAMI/RIZIV). Framed as a pyramid with three levels of validation for patient-facing mobile apps that integrate into the healthcare system and allow healthcare professionals to diagnose, apply therapy, or monitor patients remotely, the platform is now managed by Belgian medical technology industry associations beMedTech and Agoria, with validation decisions and reimbursement approvals made by public authorities.

However, all of the apps that reached the top M3+ phase of the pyramid and became reimbursable in January 2025 fall within a single area of application: tools that help hospitals and cardiologists remotely monitor heart failure patients after hospitalization and guide therapy decisions.[117] These include FibriCheck, a digital diagnostic app that allows patients to use the smartphone sensor to assess heart rhythm disorders, as well as other tools monitoring ePRO and vitals data, such as BeWell Well@Home, Comarch HomeHealth 2.0, Comunicare,

Healthentia, MoveUP, and Remecare (now also Medtronic CareLinkSystem).[118,119]

This reflects mHealthBelgium's adoption of a care-pathway-based approach — similar to NICE in the UK — where multiple digital solutions in a functional category are assessed for use within a "care path." Likewise, the first health technology assessments are prioritized on solutions that can demonstrate significant impact on patient care and integrate into the healthcare system. Beyond the first guidance, "Telemonitoring and therapeutic guidance in cases of chronic heart failure," various sources indicate that reimbursement categories will soon expand to include outpatient monitoring of cancer patients, Holter recording for cardiac patients, and remote monitoring for patients with obstructive sleep apnea and diabetes.[120]

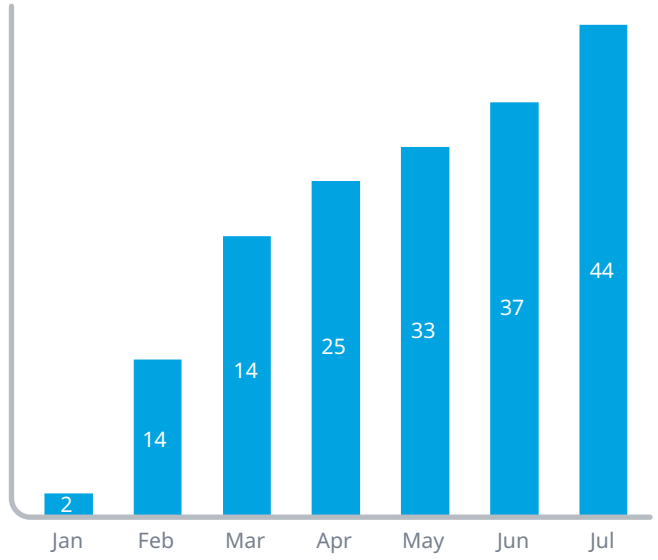
Manufacturers progress their product through these levels where their attainment of:

- **Level 1 (M1)** indicates that an app meets baseline criteria as a CE-certified medical device, complies with the European Union's General Data Protection Regulation (GDPR), and has been registered with the Federal Agency for Medicines and Health Products (FAMHP) to enable therapeutic vigilance.
- **Level 2 (M2)** adds requirements to meet Information and Communication Technology (ICT) criteria for app interoperability and secure connectivity to the eHealth platform, enabling secure exchange of health data within Belgium's federal network.[121] At this stage, companies are also required to submit clinical evidence and evidence of socioeconomic impact — demonstrating the app's added value or relevance in the care pathway and potential budgetary impact on healthcare costs and outcomes — to INAMI/RIZIV for evaluation to gain reimbursement.
- **Level 3 (M3)** confirms that the app has demonstrated sufficient socioeconomic evidence and has been granted reimbursement by INAMI/RIZIV — either as temporary funding **(M3-)** or definitive funding **(M3+)**.

Although Belgium offers a form of national reimbursement for medical apps — and in theory can provide temporary reimbursement for innovative applications with preliminary evidence — no apps currently hold M3- status. Other challenges for manufacturers seeking reimbursement also remain. Reimbursement is paid to hospitals under a bundled payment model, where the cost of the mobile app or digital therapeutic (DTx) is not carved out, and as a result, how the reimbursement payment is divided must be negotiated individually between each hospital and the technology vendor.[122] And on the provider side, only care facilities that sign a reimbursement agreement with INAMI/RIZIV — confirming their care model and staffing meet the requirements for the specific application (e.g., remote monitoring) — are eligible for reimbursement. Since the launch of the first covered products for heart failure monitoring, 44 hospitals have signed the agreement — which possibly represents around 60% of the 74 medical centers with certified heart failure staff that might be eligible (Exhibit 16).[123,124]

> *"Les Cliniques de l'Europe followed heart failure patients via telemonitoring for four years and calculated how much less the State would spend if it did this for all heart failure patients in Belgium: the savings would be around 28.7 million euros per year. Funds that could help many other patients."* [118]
>
> *— beMedTech*

Exhibit 16: Cumulative number of Belgian Centers participating in chronic heart failure telemonitoring by start date



Source: IQVIA Institute, Jul 2025 ; INAMI/RIZIV. Centers that have joined the convention/ "Remote care: Telemonitoring and therapeutic guidance in cases of chronic heart failure. Accessed Aug 25, 2025. Available from: https://www.inami.fgov.be/SiteCollectionDocuments/liste_telesurveillance_insuffusance_cardiaque_lijst_telemonitoring_chronisch_hartfalen.pdf

Notes: Around 74 heart failure centers exist according to Belgian Working Group on Heart Failure.

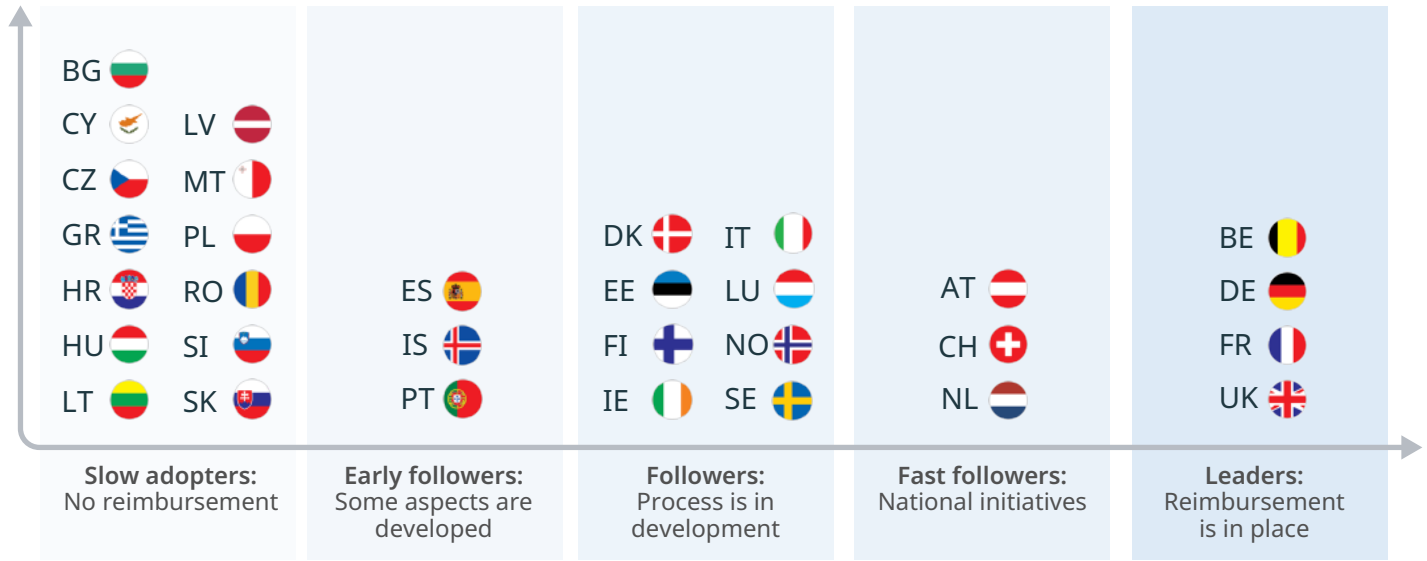
Fast followers in Europe

Other European countries too have taken steps to advance their approach to digital health solutions, with Austria and the Netherlands among a set of fast followers working to catch up to leaders through national initiatives to create routes to reimbursement, and others like Sweden and Switzerland similarly advancing (Exhibit 17).

In the Netherlands, the Ministry of Health, Welfare, and Sport (VWS) launched the Digizo.nu platform in 2023 as part of the Integraal Zorgakkoord (IZA) to evaluate digital and hybrid care technologies and accelerate their integration into healthcare. Leveraging a health technology assessment approach like Belgium and the UK, Digizo.nu announced 29 planned assessments as of August 2025, aimed at identifying evidence gaps and enabling real-world evidence generation.

However, unlike most pathways, Digizo.nu also aims to subsequently play an active role in scaling use of recommended products and aiding the transformation of current care processes into digital or blended care

Exhibit 17: Archetypes of European countries in developing reimbursement processes for digital health



Source: IQVIA Medtech. Regulations and Reimbursement for Software as a Medical Device in Europe Part 3 — Reimbursement of SaMD in Europe. Dec 2023. Available from: https://www.iqvia.com/library/white-papers/regulations-and-reimbursement-for-software-as-a-medical-device-in-europe-part-3 (adapted).

formats. It intends to identify system-level barriers to adoption and present them to stakeholders — including insurers, providers, and policymakers — to problem solve together through a joint Plan of Action.

The first two assessments to progress evaluate various mental health solutions across key dimensions, including their certification, accessibility and their ability to provide information security, privacy, and supplier support.[125,126] These include:

- **"Treatment with digital EMDR in mental health care"** which assessed Moovd (WeMind) and Psylaris — technologies that use Eye Movement Desensitization and Reprocessing (EMDR) to treat anxiety disorders and post-traumatic stress disorder (PTSD) via virtual reality and digital platforms, and
- **"Treatment through eHealth platforms"** which assessed Minddistrict, Karify, Therapieland, and Embloom. The evaluation found that eHealth platforms were equally effective as face-to-face care in reducing symptom severity for depression, anxiety, and autism, but were less effective for addiction (no conclusion for personality disorders).[127]

Funding for these efforts is supported by the Beleidsregel Innovatie (BRI) — the Policy Rule Innovation for Small-Scale Experiments — and other initiatives, including a ZonMw competitive grant under the Versnellingsimpuls voor Hybride en Digitale Zorg en Welzijn program (Acceleration of Hybrid and Digital Care and Welfare), totaling €3.5 million to support strategy development, implementation, scaling, and evaluation projects.[128]

South Korea

In Asia, both Korea and Japan have grown in maturity, having progressed their approval and reimbursement pathways over the past few years and building on efforts to standardize assessment. South Korea's Ministry of Food and Drug Safety (MFDS) began to standardize its assessment of digital health solutions in 2020 with the release of its *Guideline on Review and Approval of Digital Therapeutics*, which laid out definitions, assessment criteria, and clinical trial guidance for specific therapeutic areas.[129,130] And, in January 2025, the *Digital Medical Products Act (DMPA)* also came into effect, establishing quality control standards, inspections, and performance certification requirements for digital medical products.[131]

Aiming to accelerate the approval and reimbursement of innovative medical devices, Korea introduced the Integrated Review and Assessment System (IRAS) pathway in October 2022, open to a range of SaMD. These include digital therapeutics, virtual reality products, biosensor-based tools, AI or computer aided digital diagnostics, and big data technologies. Similar to Germany's DiGA and France's PECAN, IRAS also grants access to temporary reimbursement — for up to three years but extendable to five — to technologies that have demonstrated efficacy and feasibility but still lack robust clinical evidence, providing a more rapid route to clinical use and partial reimbursement.[132]

After initial assessment by NECA (National Evidence-based Healthcare Collaborating Agency) to confirm the device technology is innovative and eligible for temporary national reimbursement, products obtain concurrent regulatory review by MFDS and reimbursement review by HIRA (Health Insurance Review and Assessment Service).[133] Similar to the UK's EVA pathway, IRAS provides a route to more widespread clinical use and aids the generation and collection of real-world data to support eventual full review by HIRA via the New Health Technology Assessment (nHTA) pathway and permanent reimbursement by the National Health Insurance Service (NHIS).

Although digital health solutions are still grouped together with other innovative medical technologies under IRAS, already six digital therapeutics were approved via the pathway by mid-2025.[134] Aimmed's Somzz and Welt's SleepQ mobile digital therapeutics, both targeting insomnia, were the first to receive approval in early 2023 and temporary reimbursement at the end of that year.[134–136] Two additional digital therapeutics were approved in 2024 — VIVID Brain by Nunaps, designed to treat visual impairments resulting from brain damage, and EasyBreath by Share & Service, supporting respiratory rehabilitation.[133] More recently, Neurive's SoriCLEAR for tinnitus and HAII's Anzeilax designed to treat Generalized Anxiety Disorder (GAD) joined the list of approved digital therapeutics. Additionally, the pathway is actively used and, as of mid-2025, developers had reportedly submitted upwards of 17 clinical trial plans spanning 12 conditions, including insomnia, addiction, ADHD, mild cognitive impairment, and developmental disorders.[137]

Japan

Japan has likewise progressed its reimbursement of digital technologies and has taken unique steps to incentivize the development of domestic SaMD technologies and attract foreign manufacturers. Its initial "*Digital Transformation Action Strategies for Healthcare (DASH) for SaMD*" initiative from 2020, a joint effort by the Ministry of Economy, Trade, and Industry (METI) and the Ministry of Health, Labour and Welfare (MHLW), marked a significant milestone. This program established a dedicated office to provide regulatory consultation for SaMD developers and introduced a priority review pathway for innovative digital health technologies, including digital diagnostics and therapeutics. These measures were designed to accelerate regulatory processes and reduce barriers for companies seeking market entry.

However, despite these advancements, under DASH for SaMD, approval for marketing did not automatically translate into coverage. Instead, inclusion in the National Health Insurance (NHI) Price List continued to be determined on a case-by-case basis, requiring individual evaluation by reimbursement authorities. This meant that even after a SaMD product received regulatory clearance, coverage was not guaranteed, creating uncertainty for manufacturers and limiting access for patients.[138,139]

To address these gaps, "DASH for SaMD 2" was introduced in January 2024 under the Pharmaceuticals and Medical Devices Agency's (PMDA) fifth mid-term plan (2024–2028). This updated strategy aims to create a more structured and predictable pathway from

> ***"The key to gaining market share in the global market is competing with SaMD that combine Japan's strengths in diagnostic equipment with digital technology, and commercializing devices that solve unmet medical needs... [The SaMD] industry will grow to be one of the world's top internationally competitive industries, as a mechanism to evaluate innovative products is being considered."*** [143]
>
> *— Third Report of the Committee on New Direction of Economic and Industrial Policies*

> *"Consumer advertising of medical devices used by medical professionals is prohibited in Japan. However, to enable consumers to choose their appropriate treatment method, this prohibition was lifted for CureApp HT in March 2024."* [145]
>
> *— Kohta Satake, M.D. and Representative Director and CEO of CureApp*

regulatory approval to insurance coverage. Mirroring global trends, a key feature of the revised framework is the introduction of a two-stage approval process.[140] The first stage offers early conditional approval, enabling products with preliminary evidence to enter the market sooner and generate real world data to confirm their clinical significance, while the second stage provides full approval after confirmatory evidence is submitted, with expedited consultation and review from PMDA to streamline timelines.[141] In addition to regulatory acceleration, DASH for SaMD 2 sets ambitious goals: a targeted six-month review timeframe, enhanced collaboration between regulatory and insurance authorities, and clearer commercialization pathways for developers.[140,142]

Japan has approved at least five digital therapeutics to date, along with various other digital health solutions. Between 2021 and 2024, three DTx were approved: CureApp HT for hypertension, CureApp SC for smoking cessation, and Susmed CBT-I for insomnia, followed by CureApp Alcoholism and Shionogi's ADHD game-based therapeutic, ENDEAVORRIDE in 2025. Additionally, several health assessment tools have been approved, including smartwatch-based features — such as Apple's Atrial Fibrillation History, Sleep Apnea Notification, Hearing Assist, and Hearing Check; the RST Calculation Program, which monitors a novel respiratory stability indicator (RST) to detect early signs of heart failure worsening; MIREVO, which screens for dementia using eye-tracking technology; and the surgical and radiological support tool, Medis QFR.[144]

Latin America

Finally, in Latin America, countries such as Brazil and Mexico remain in the early stages of developing structured assessment frameworks for digital solutions, similar to Spain and Italy, where standardized frameworks are lacking and reimbursement is largely ad hoc and managed regionally. Brazil has outlined a long-term vision through its ESD28 Digital Health Strategy (2020–2028) and monitoring plan and ANVISA approved its first digital therapy platform, SleepUp, designed to manage insomnia and combines cognitive behavioral therapy (CBT) with wearables and analytic algorithms for personalized care.[146] National reimbursement remains limited, though some telemedicine consultations for remote patients are covered, and private insurers offer partial coverage for digital health services.[147]

Reimbursement and uptake in the United States

+ **In the United States, a fragmented payer landscape has made it difficult for digital health solutions to scale and gain reimbursement nationally.**
+ **Billing codes have been pivotal in facilitating the use of digital solutions in care, while offering varied reimbursement opportunities depending on solution type, payer, therapy area, and care setting.**
+ **Commercial payers now cover select digital care programs and well-evidenced digital therapeutics they deem medically necessary but may require evidence of patient adherence and measurable clinical improvement to continue reimbursement.**
+ **Medicare consistently covers remote monitoring but lacks a defined benefit category for SaMD, limiting the ability of digital therapeutics to gain coverage and access new reimbursement policies and accelerated pathways for innovative devices such as the TCET pathway.**
+ **Employers also remain an important source of funding for digital care programs, providing them as wellness benefits to employees to offset productivity costs of insomnia and musculoskeletal pain and support mental health.**
+ **In 2025, CMS expanded Medicare reimbursement for digital therapeutics beyond durable medical equipment to include SaMD by enabling providers to "buy and bill" for the "supply" of digital mental health treatment devices incident to care and may extend this approach to other solution types.**
+ **The push by CMS toward value-based care by 2030 may create new opportunities for digital care providers, who already use new care management codes that permit team-based care partially furnished by non-physician clinical staff.**
+ **As of 2025, 56 billing codes used in digital care allow non-physician staff to deliver services but year-over-year use of codes permitting incident-to billing grew 36% compared with 10% for direct billing.**
+ **Some State Medicaid plans and federal systems, including the Department of Veterans Affairs, contract with manufacturers of digital health products and list them on preferred drug lists and federal procurement catalogs.**

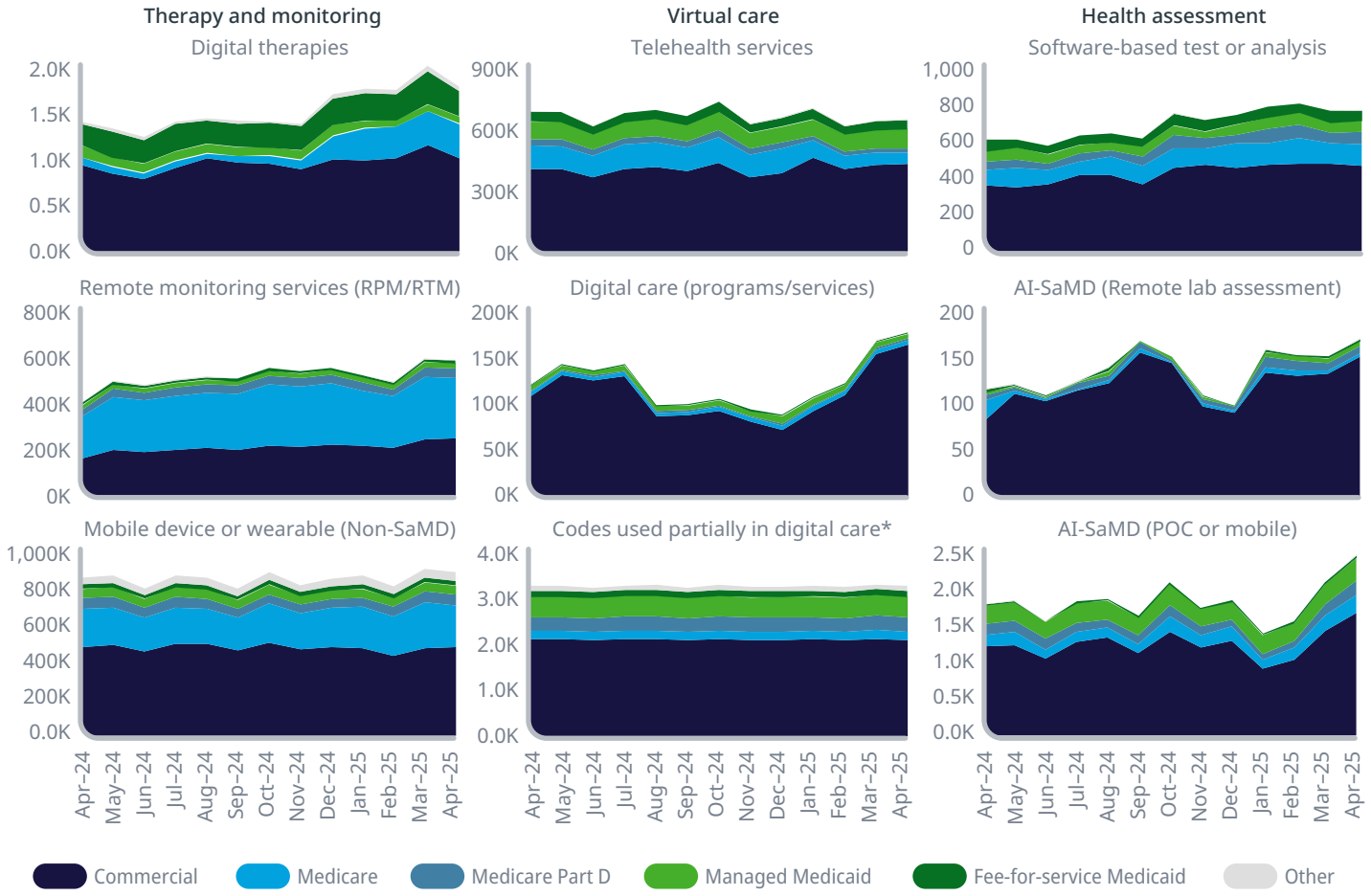
VARIED OPPORTUNITIES BY SEGMENT

In the absence of a centralized national reimbursement pathway, various payers in the United States, including commercial health plans, federal programs, state agencies and even employers make separate decisions on whether to fund digital health solutions. This has notably made it challenging for digital solutions to scale.

In the past few years, billing codes created by the Centers for Medicare & Medicaid Services (CMS) and the American Medical Association (AMA) to reimburse providers for use of digital solutions and related services have played a central role supporting their gradual integration into patient care (see Billing for digital care in the U.S. Callout). Some commercial insurers have also requested that custom billing codes be created to facilitate reimbursement of their contracted digital solution providers.

There are now 117 billing codes in the U.S that tie specifically to the use of software-based technologies such as SaMD, SiMD and AI-SaMD and more than 300 in total that facilitate their use and those of mobile solutions (Exhibit 12). However, as codes have been created for some digital health solution types but not others, commercial opportunities currently vary by payer type, product category, therapy area, and care setting (Exhibit 18).

Exhibit 18: Use of digital solutions types and related services by pay type (*based on a sample of medical claims*)



Source: IQVIA Institute Digital Health Billing Code Database, Aug 2025; IQVIA Medical Claims Data, data extracted Aug 10, 2025.

Notes: Data trend should be considered directional. Due to distinct market dynamics data capture is unknown. Sample size and capture vary by product type. *Counts only the used of these codes delivered via telehealth excepting non-face-to-face service codes. Other includes unspecified, blank and cash which appear linked to device supply and telehealth. Managed Medicaid includes Medicare Supplement, Medigap, State Assistance. Federal employers including the VA reflected in Third Party. Rx claims for digital therapies are excluded from this view, where some are cash pay. Digital therapies and Software-based test categories include SaMD and SiMD with or without associated hardware/DME components. Digital therapies include clinical therapy tools. Point-of care (POC).

Commercial insurers, which cover the majority of individuals, have generally moved more rapidly than public payers to pilot and reimburse digital health solutions used at home or at the point of care. Medical claims data show they are faster to cover digital care programs (e.g., Omada, Hinge Health, Teladoc, and others), AI-enabled tools for health assessment and radiology, and, to a lesser extent, digital therapeutics.

However, public payer coverage for digital therapeutics has grown recently, and Medicare — which is the primary insurer for elderly patients who may have chronic conditions — leads significantly in covering remote monitoring (Exhibit 18). Medicaid also appears to cover some app-linked insulin delivery systems, such as Omnipod DASH, and has begun to receive a small number of claims for digital therapeutics — notably, mental health treatment devices (DMHT) for substance abuse, amblyopia, and some clinical therapies supporting neuro-rehab and mental health.

Such heterogeneous payer policies complicate the ability for developers to scale up their solutions, and in many cases, the collective volume of use remains low and insufficient for products to remain commercially viable. However, some leading solutions

with robust evidence have succeeded, gaining traction and outstripping the overall trend, such as some digital-first care programs commonly included in employer-negotiated wellness benefits.

REIMBURSEMENT AND POLICY SHIFTS BY PAYER TYPE

Commercial payers and employers

Most leading commercial payers now reimburse for one or more digital health solutions but still classify the majority as investigational, citing insufficient evidence of clinical benefit (or durable/consistent clinical efficacy). They make reimbursement decisions on a product-by-product basis and as a result, billing remains limited for key categories of software-based tools — including the majority of prescription digital therapeutics (PDTs) — likely reflecting limited coverage.

Coverage for digital care programs — to help employees with sleep, chronic conditions, musculoskeletal concerns like back pain, mental health needs or support women's health — appears to be more substantial. This is likely due to employer interest in offering select digital solutions as wellness benefits for employees, which has provided a growing source of funding over the past few years. Self-insured employers, particularly, stand to gain if digital solutions offset healthcare costs or improve worker productivity.

As digital health solutions have entered the U.S. market, the Peterson Health Technology Institute found that three-quarters of purchasers in 2024, including health plans, employers and health systems, reported increased spending on digital solutions in the prior two years, and 43% of them cover solutions spanning six or more clinical conditions.[7] They cited growth in consumer demand and the potential for solutions to improve health outcomes and offer cost savings as key drivers.[7]

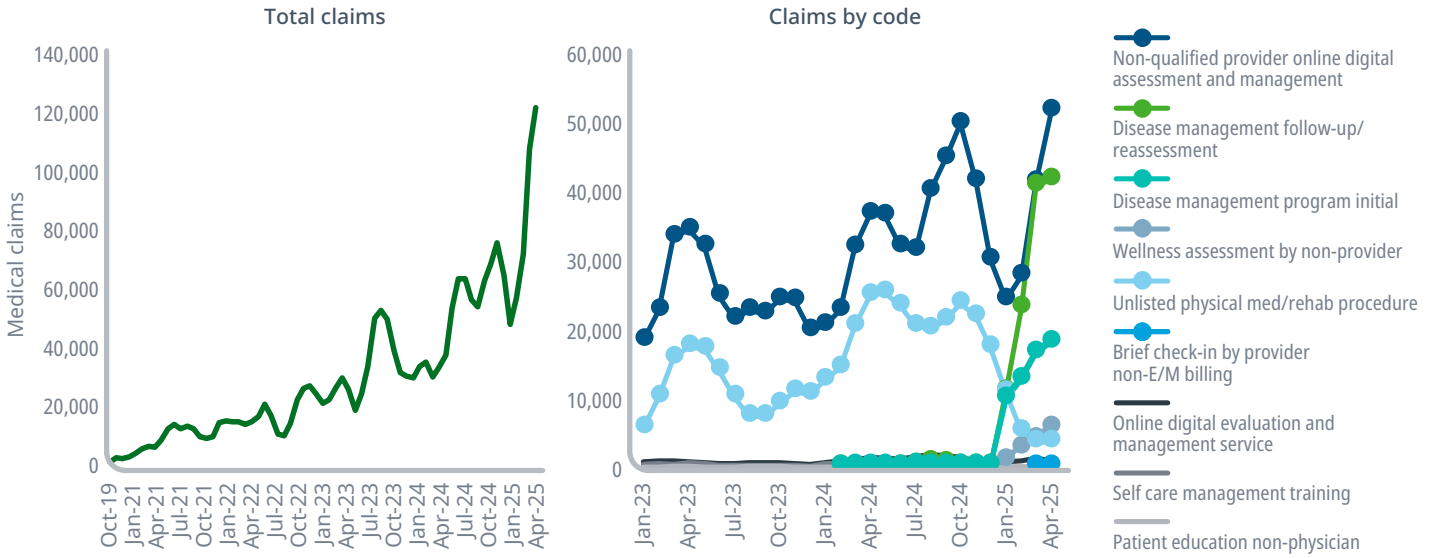
The uptick in consumer interest also led some payers and PBMs to assemble digital care formularies for optional uptake by employers (via opt-in riders or add-ons). Publicly disclosed examples include United Healthcare offering Kaia Health for musculoskeletal conditions in employer plans and Evernorth partnering with several digital therapeutics companies like

ANALYSIS OF DIGITAL HEALTH MEDICAL CLAIMS

Exhibits in this section are based on an analysis of IQVIA Medical Claims in the United States using the Digital Health Billing Code Database, which was compiled by the IQVIA Institute to facilitate such claims analyses. This database contains codes maintained by the AMA and CMS on behalf of various payers that enable providers and suppliers to bill for and request reimbursement for various elements of digital-enabled healthcare. It includes billing codes created for various software-based solutions, sensor-based mobile devices, digital care programs and services, along with codes related to remote patient care or virtual care services — e.g., telehealth, telemonitoring and communication technology-based services (CTBS). Approximately 25 custom fields clarify how the products and services associated with each code can be used and billed, including incident-to billing by non-physicians, known products that bill through each, etc.

Due to the distinct market dynamics in this market, all data should be considered to be an unknown sample of claims and their depiction here is meant only to elucidate directional trends in digital health use in the U.S. market. In some cases where noted, service claims not specific to remote or virtual care have been narrowed solely to their use via telemedicine. Additionally, because this specific database contains unadjudicated Medical Claims, billing is being displayed as a proxy for reimbursement and it is likely that not all billed claims were reimbursed.

Exhibit 19: Monthly medical claims billed by a leading musculoskeletal digital care provider



Source: IQVIA Institute, Jul 2025; IQVIA Medical Claims Data, data extracted Jul 19, 2024.
Notes: Data trend should be considered directional. Due to distinct market dynamics data capture is unknown.

Omada Health, Propeller Health and, formerly, Pear Therapeutics.[148] Self-insured employers also negotiate directly with digital care providers to include their digital care programs as wellness benefits. Finally, some payers have moved to create their own digital-first care solutions rather than pay for commercial offerings — like Anthem's "Learn to Live" internet based cognitive behavioral therapy (iCBT) program and United Health Group's AbleTo's Self Care+ program — a potential source of competition.[68,149]

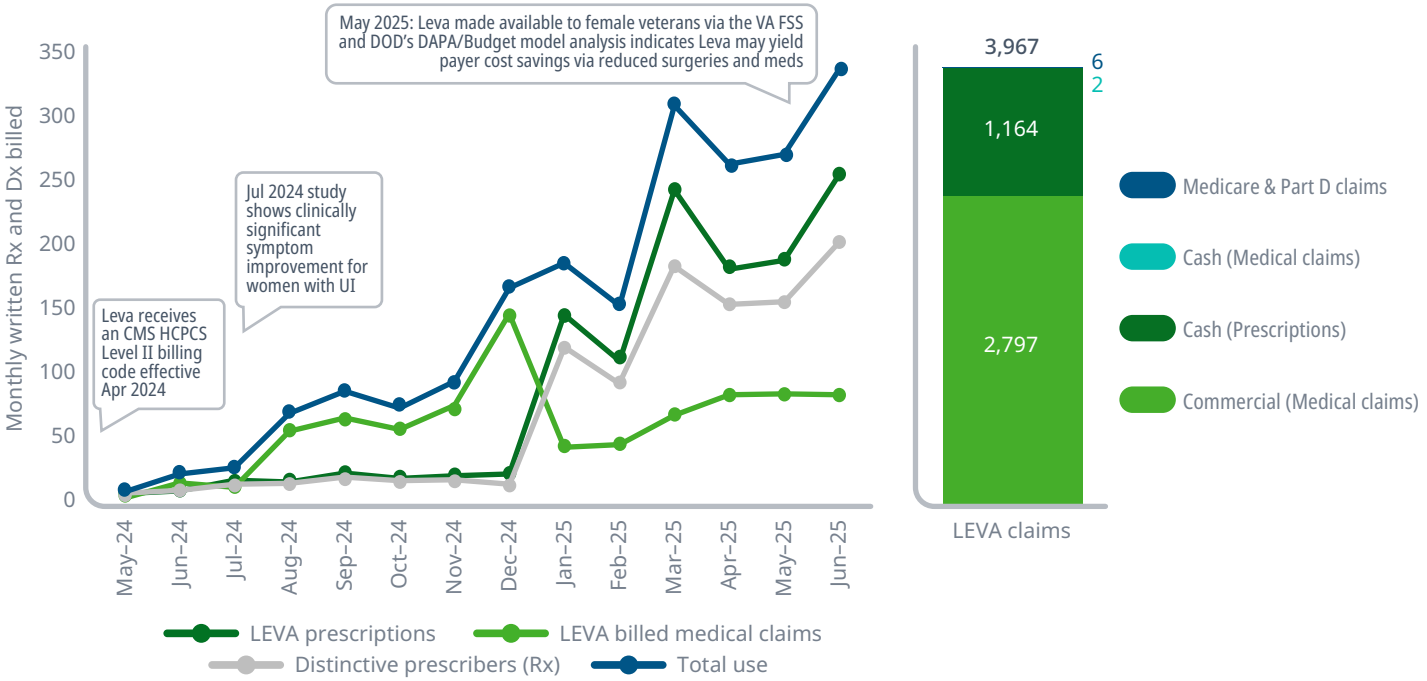
Although it is unclear whether the growing use of digital care services has been a driver, CMS has created S-codes to accommodate private payer billing, administration and tracking of disease management programs, lifestyle modification programs for the management of coronary artery disease, diabetic management programs, cardiac rehabilitation programs, pulmonary rehabilitation programs and vestibular rehabilitation programs — all of which could be used by digital care providers in theory.

As the use of digital-first care programs has grown, some leaders have emerged and — notably in the musculoskeletal space — have achieved continued adoption, reimbursement and business growth (Exhibit 19). One among them, Hinge Health, has called out its success in partnering with leading health plans including Aetna, Anthem, Blue Cross Blue Shield, Cigna, Kaiser, Medicare, and UnitedHealthcare, among others.[150]

Commercial payers cover some digital health solutions that are dispensed and reimbursed like drugs under their pharmacy benefit — such as PDTs or wellness apps offered on PBM digital formularies (that may be used in digital care weight management programs like Lark, Weight Watchers and) — while solutions administered or used in clinical setting and digital first care programs, or which have negotiated formulary inclusion under employer plans more often receive device-like reimbursement under the medical benefit. It is also possible that the pharmacy channel is being used to facilitate dispensing of DTx within the bounds of digital care, as some appear to be filled with a zero or one cent cost.

In some cases, prescription digital therapeutics initially only available through the pharmacy channel have also been issued private-payer medical claims billing codes that facilitate reimbursement under medical

Exhibit 20: U.S monthly prescriptions and billed medical claims for Leva Pelvic Health system



Source: IQVIA Institute Digital Health Billing Code Database, Sep 2025; IQVIA LAAD, Sep 2025; IQVIA Medical Claims Data, data extracted Sep 21, 2025.
Notes: Data trend should be considered directional. Due to distinct market dynamics data capture is unknown. Federal employers including the VA reflected in Commercial (Third Party).

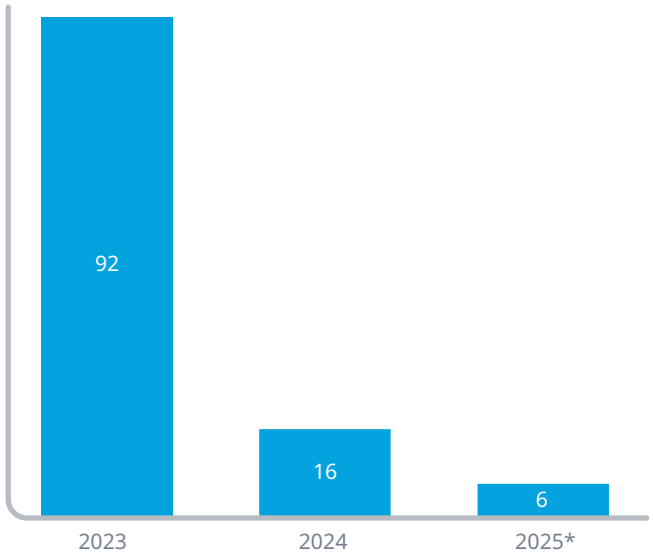
benefits, as is the case with Leva Pelvic Health System, an intravaginal motion sensor biofeedback system to strengthen pelvic floor muscles for patients with incontinence. Such products may now be dispensed and/or reimbursed through both channels, with the potential to be reimbursed within the bounds of digital care programs. In practice, this may mean a patient seeking a PDT prescription may obtain one directly via a virtual provider/prescriber like UpScript, and pay out of pocket, while Commercial and Public payers may be more likely to pay for contracted solutions under medical benefits.[33] The result in some cases is that the pharmacy channel may show all cash-pay while medical claims track the reimbursed dispensing (Exhibit 20).

Although a growing number of payers had begun to reimburse DTx flowing through the pharmacy channel when we examined this data in our Digital Health Trends 2024 report,[1] this trend appears to have reversed, with very few pharmacy-prescribed DTx now reimbursed and most coverage occurring under the medical benefit (Exhibit 21) or through specialty pharmacies not captured by IQVIA.

Our published analysis of adjudicated prescription data through May 2024 showed that limited reimbursement of PDTs forced patients to pay out-of-pocket to receive access — resulting in 91% of pharmacy-dispensed PDTs being paid in cash — and hindered access.[1] This continues to be the case through mid-2025 (Exhibit 22).

Though leading commercial payers have built portfolios of partner digital care providers, they still have varied approaches to digital therapeutics. Some individual payers initially took leadership positions in covering digital therapeutics, as regional commercial payer Highmark did in 2022 with its decision to reimburse most FDA-cleared digital therapeutics prescribed by licensed healthcare professionals.

Exhibit 21: Number of payers reimbursing a pharmacy-dispensed prescription digital therapeutic



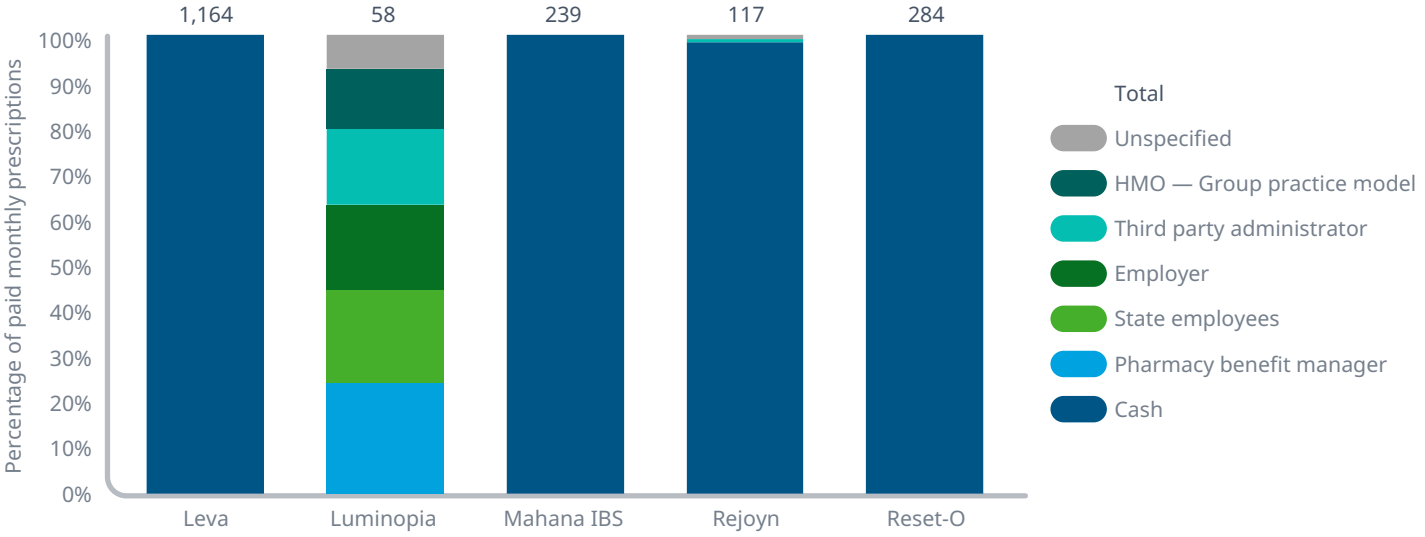
Source: IQVIA Institute, Aug 2025; IQVIA Medical Claims data ending Jul 2025.

However, most other large payers cover only a few patient-facing solutions they deem medically necessary, and classify the rest as experimental.[151–153]

Cigna, for instance, covers Leva Pelvic Health System as medically necessary for women with urinary incontinence.[154] Additionally, as it has become apparent that not all individuals engage enough with mobile apps to obtain a therapeutic effect, even payers that do cover some as medically necessary, may now also require proof of sustained patient adherence to therapy and/or continued improvement to maintain reimbursement. For instance, Anthem considers some potentially medically necessary including digital mental health treatment devices (DMHTs), Nerivio remote neuromodulation device for migraines, and CureSight/RevitalVision for amblyopia in the pediatric population, however — as an example — requires proof of adherence and improvement in visual acuity for amblyopia.[155,156] Some payers also cover diagnostic aids such as Drowzle Pro to screen for sleep apnea and Halo AF for atrial fibrillation detection, along with other AI-enabled diagnostic tools.

In contrast, Highmark continues to cover a broad range of digital therapeutics, including Luminopia for pediatric amblyopia (lazy eye), RelieVRx for chronic lower back pain, Stanza (Swing Care) for fibromyalgia symptoms, MamaLift Plus for postpartum depression, SleepioRx for insomnia, and DaylightRx for generalized anxiety disorder. Other covered solution types include digital diagnostic tools like Canvas Dx for autism screening, the GoCheck Kids photoscreening app for amblyopia detection, and Natural Cycles for predictive contraception.[157,158]

Exhibit 22: Paid monthly prescriptions by model type for pharmacy-dispensed PDTs in the U.S., Jan 2024–Jul 2025



Source: IQVIA Institute, Jul 2025; IQVIA LAAD Prescription data final through April 2025.

Finally, payers offer some specialized health plans that include access to partner digital solutions such as digital therapeutics (DTx) and virtual care. These plans include virtual-first health plans (VHPs) meant to appeal to employers and other meant to serve individuals under Medicare Advantage and Managed Medicaid with chronic conditions, social challenges, special needs, mental illness, or substance use disorders. These include:

- **Virtual-first health plans (VHPs)**, which prioritize virtual care as the initial point of contact for members and may include chronic condition management, exercise and prevention programs, substance abuse counseling, nutrition coaching and behavioral and mental health support.[159,160] Some offer wellness incentives tied to the use of wearable devices.[161]
- **Addiction recovery plans**[162] (Managed Medicaid Dual eligibles), which focus on substance use disorder (SUD) treatment and typically include recovery services and behavioral counseling, virtual programs and digital care apps for alcohol and substance use behavior change and more comprehensive support.
- **Behavioral health and comprehensive care plans**, which cover mental health services, focus on care coordination between physical and behavioral health providers to address behavioral, social, and environmental determinants of health, and sometimes include apps and digital care.[163]
- **Chronic condition/care management**, which are designed to reduce costs for individuals with chronic or complex conditions, often within value-based care models. These plans support whole-person care and optimize care delivery through coordinated teams that may include nurse care managers, social workers, health educators, pharmacists, dietitians, and mental health specialists.[164]
- **Dual-Eligible Special Needs Plans (D-SNPs)**[165] Medicare Advantage plans for individuals eligible for both Medicare and Medicaid, offering coordinated, comprehensive coverage for high-need populations.

Public payers

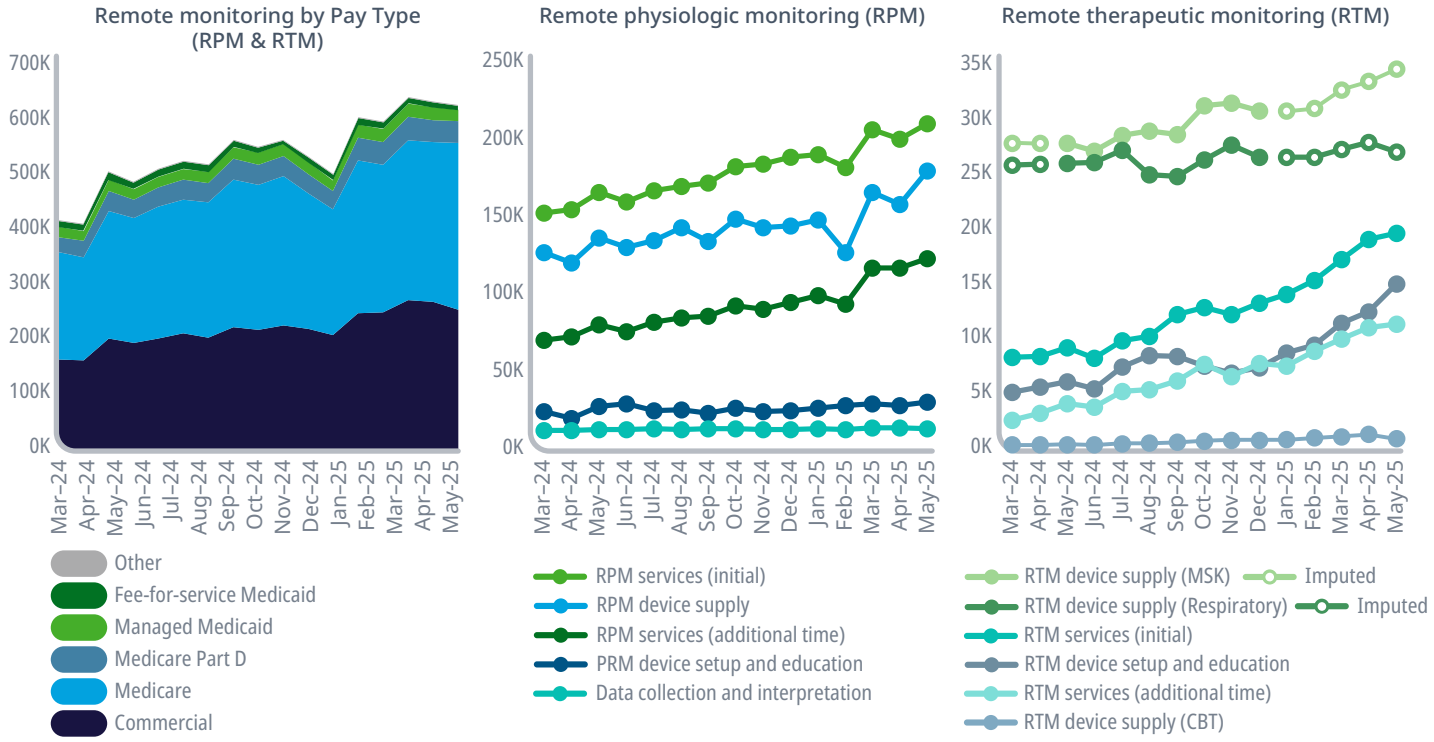
Medicare

At the federal level, Medicare reimburses a growing range of health services supported by digital tools but still lacks a dedicated benefit category for Software as a Medical Device (SaMD) — the classification under which many digital health solutions and digital therapeutics fall. This gap has hindered Medicare's capacity to cover these devices directly and limited the ability of digital health companies to serve the Medicare population. It also excludes SaMD products from accelerated coverage mechanisms designed for innovative technologies, such as Transitional Coverage for Emerging Technologies (TCET). Over time however, CMS has gradually introduced workarounds to allow SaMD products to be covered within existing pathways.

Although Medicare, like other payers, often declines to cover novel products and services issued temporary codes, it notably provides reimbursement for the vast majority of established services and technologies granted Category I code by the AMA. And in fact, once solutions are deemed established, coverage by Medicare may then outstrip that of Commercial payers. For instance, a study of CPT billing codes published by the AMA at the end of 2023 found that Medicare and Medicare Advantage plans covered all 21 digital medicine services, while coverage of these services under commercial health plans was not as expansive coverage.[87] For instance, remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) are established services with Category I codes. While physician-paid claims for remote monitoring have continued to grow since these codes were introduced in 2018 and 2022, respectively, they are more commonly billed to Medicare than commercial payers (Exhibit 23).

Additionally, AMA may create new Category I CPT codes when an innovative technology becomes well-established and accepted in medical practice. As the use of AI-enabled diagnostic tests have grown in the private sector (Exhibits 24 and 18), the first Category I CPT codes have been created to

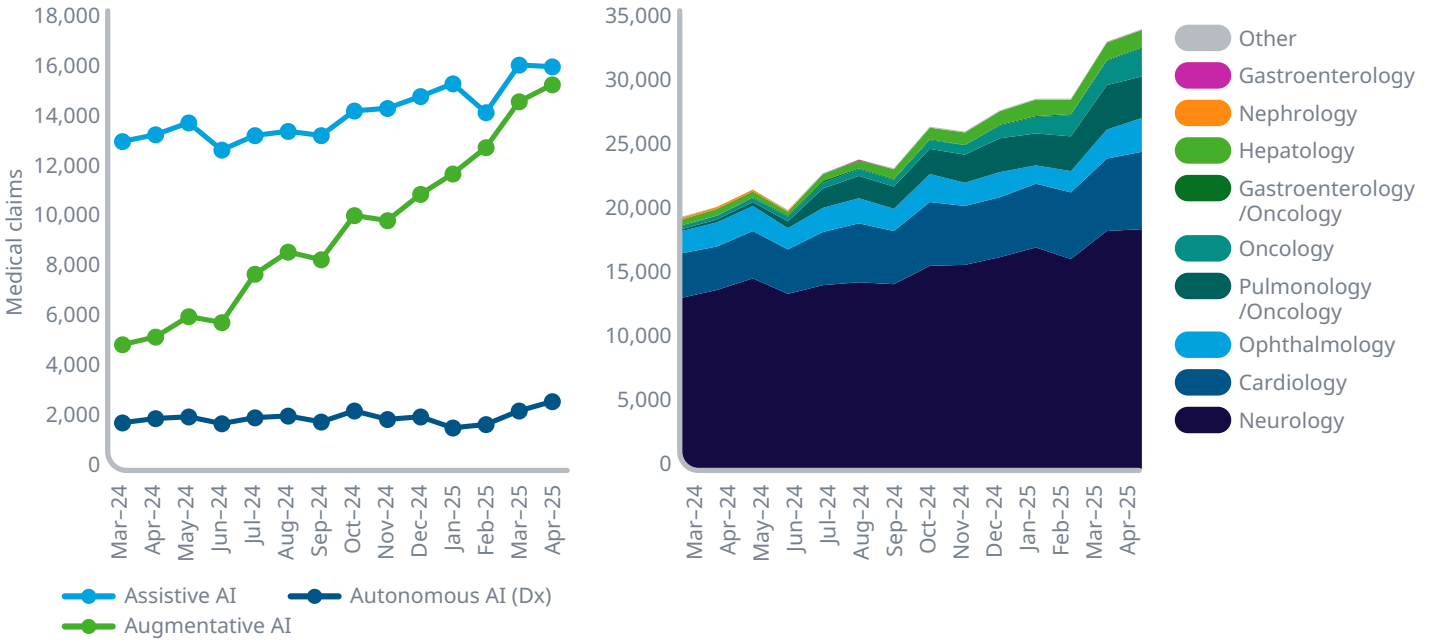
Exhibit 23: Use of remote patient monitoring by type and therapy area (*based on a sample of medical claims*)



Source: IQVIA Institute Digital Health Billing Code Database; Sept 2025; IQVIA Medical Claims Data, data extracted Sep 21, 2025.

Notes: Data trend should be considered directional. Due to distinct market dynamics data capture is unknown. Data trend for respiratory and musculoskeletal RTM codes was imputed from Mar-Apr 2024 and Jan-May 2025 due to a data trend break where noted. Data were imputed based on the trend of other data for the billing code unaffected by the trend break. Muskuloskeletal (MSK). Cognitive behavioral therapy (CBT).

Exhibit 24: Use of AI-enabled health assessment tools by type and therapy area (*based on a sample of medical claims*)



Source: IQVIA Institute Digital Health Billing Code Database; Aug 2025; IQVIA Medical Claims Data, data extracted Aug 16, 2025.

Notes: Data trend should be considered directional. Due to distinct market dynamics data capture is unknown.

accommodate AI-enabled and algorithmic tools in the 2026 Medicare Physician Fee Schedule. These include ones for coronary arterial plaque analysis, cardiac risk stratification based on perivascular fat analysis, burn classification using multispectral imaging, and acoustic/ECG-based cardiac dysfunction detection.[166,167] This shift has generated some recent excitement — in part because it indicates they are no longer perceived as experimental but rather mature technologies, and also because they are then more likely to be reimbursed by Medicare and other payers.

Coverage pathways for digital health

Digital developers including digital therapeutics have been able to gain coverage for their solutions through several key pathways including:

- **Durable Medical Equipment (DME)**: for products with proprietary hardware that meet statutory criteria.
- **Incident-to Pathway**: for services and supplies furnished under a clinician's treatment plan. For digital health solutions these notably include:
  - **Devices furnished incident to (G-Codes)**: relating to the "supply" of digital-tools and specific associated patient management services
  - **Clinical staff services furnished incident-to**, permitting non-physician staff to furnish care under provider supervision and often via telehealth

And additional opportunities may also be available for digital care program suppliers both within Medicare, Medicare advantage and Medicaid through:

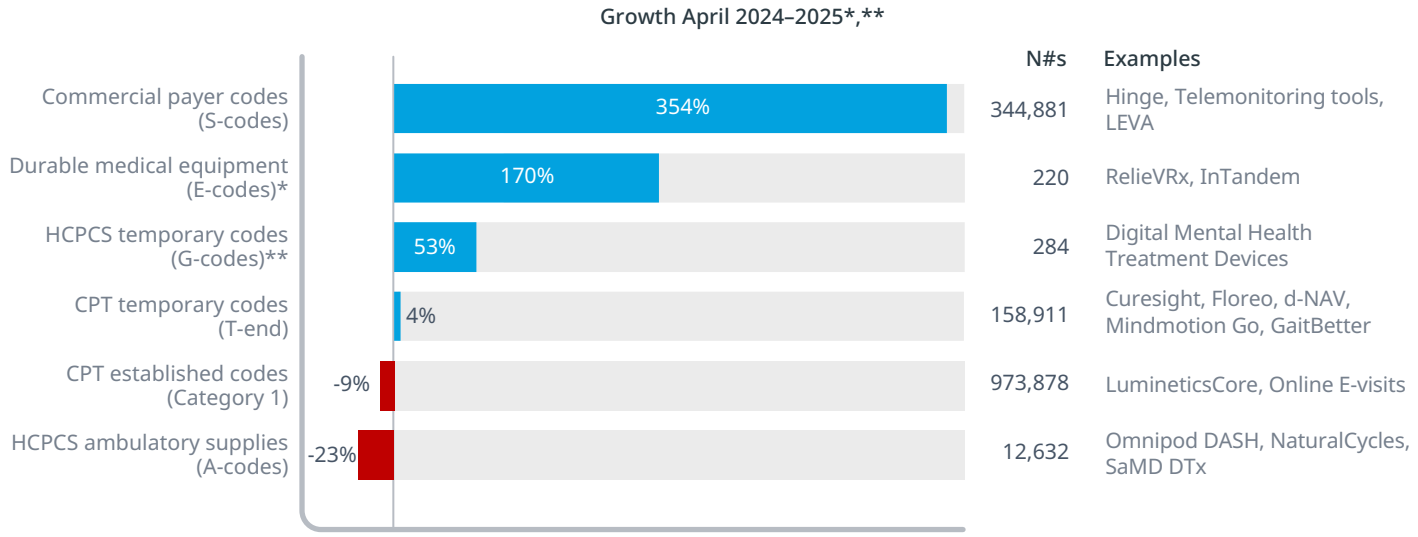
- **Care efficiency programs**: including disease prevention programs, such as MDPP, and care management, sometimes under value based care models. However, devices may not be independently reimbursed.

In each of these cases, reimbursement for digital tools and/or associated clinical services through these pathways are supported by different HCPCS and CPT billing code series that CMS and AMA issue and maintain. An examination of the relative uptake of SaMD and other mobile digital health solutions like digital therapeutics shows that products issued commercial payer codes have grown most rapidly since April 2024, followed by solutions with hardware components that have gone through Medicare's DME Pathway, followed by digital mental health treatment devices which were introduced in 2025 and are now covered under Medicare's "Incident-to Pathway" (Exhibit 25). And, at times, developers have also managed to obtain temporary codes for emerging technologies from the AMA, which sometimes cover provider services related to software-based devices (e.g., setup, education, and data collection for automated insulin dose titration products like d-NAV) but not the product itself.[168]

"We are seeing progress in integrating artificial intelligence into mainstream healthcare with the approval of several new Category I CPT codes for AI-enabled and algorithmic services in the 2026 code update. This development signals more than just formal recognition — it opens the door to reimbursement and broader adoption of clinically meaningful AI tools." [166]

— David Shulkin, Ninth Secretary, U.S. Department of Veterans Affairs

Exhibit 25: U.S. claims growth for digital therapeutics and related services by code type (*based on a sample of medical claims*)



Source: IQVIA Institute Digital Health Billing Code Database, Sept 2025; IQVIA Medical Claims Data, data extracted Sep 21, 2025.
Notes: *DME uses an October base period due to limited capture. **G-codes use effective date of Jan 2025 as a base period.

"CTA believes digital therapeutics can fit under existing Medicare benefit categories, including devices furnished incident to a physician's service (e.g., digital therapeutics furnished by providers as part of their treatment of patients) or as durable medical equipment (e.g., digital therapeutics housed in virtual reality hardware systems." [169]

— Consumer Technology Association (CTA) Sep 2023

In the treatment space, the first HCPCS codes introduced to support digital therapies included them under ambulatory medical supplies. These included A9291 in 2022 to enable reimbursement for FDA-cleared prescription digital cognitive behavioral therapies (initially for Pear Therapeutics' products) and A9292 for visual therapy (such as Luminopia). However, these codes were established without national pricing and lacked associated codes to reimburse related provider services. As a result they have been used only minimally for billing and reimbursement.

Medicare DME pathway

Since then, manufacturers of digital therapeutics that incorporate proprietary hardware have used CMS' Durable Medical Equipment (DME) pathway as a clearer path to obtain set pricing and seek reimbursement. For novel or unique products that qualify as durable medical equipment (DME) — such as digital therapeutics integrated with proprietary hardware — manufacturers may request new HCPCS codes to enable billing, or if they are not novel, they can be covered under existing ones.

While these codes are not inherently payable by Medicare, they can facilitate reimbursement and influence commercial and employer coverage.[69,170–172] Digital therapeutics designed for home use such as RelieVRx (a cognitive behavioral therapy PDT for chronic low back pain) that housed software in a virtual reality system — and InTandem (rhythmic auditory stimulation to support gait modulation) — have successfully been issued codes through the DME pathway. Those manufacturers can then either distribute products through licensed DME distributors or become Medicare Durable Medical Equipment & Medical Supplies (DMEPOS) suppliers themselves by obtaining NPI numbers like AppliedVR and MedRhythms.[69,173]

In its final benefit category determination, CMS cited several device features that supported its acceptance of AppliedVR's RelieVRx as DME, including that:[174]

- The software was locked to the device, and could therefore not be used on personal devices, nor could other non-medical software be added
- The device itself had features that drive the effectiveness of the software and deliver patient benefit and therefore no personal devices like computers or laptops could achieve the same effect with the same software or interact with both the patient and the software algorithms in the same way
- The medical software and device on which it was housed were considered integral to each and one whole device; not separate software and device (e.g. patented, modified or proprietary headsets or devices with preloaded software)
- FDA identified a special control (88 FR 983) requiring the patient-contacting devices components to be demonstrated biocompatible, indicating that the hardware and software are necessary components of the product.

> *"The medical software and the device on which it is housed are so integral to each other that we consider them to be one whole device, not software and a separate device."* [174]
>
> *— CMS DME determination for RelieVRx*

"Incident to" Device Supply G-Codes for buy-and-bill

By contrast, Software as a Medical Device (SaMD) — which may run on a mobile phone, tablet, or laptop — typically does not qualify as durable medical equipment (DME). And, without a benefit category, most digital therapeutics have lacked access to dedicated billing codes with set pricing and reliable reimbursement pathways.

To address this gap, CMS introduced a new workaround in its 2025 Medicare Physician Fee Schedule allowing SaMD products to be reimbursed as a supply "incident to" a qualified provider's established care plan.[175] Specifically, CMS introduced G-codes for digital mental health treatment devices (DMHTs). These includes only software-based devices that were FDA-cleared, approved, or granted De Novo authorization under the 21 CFR 882.5801 classification as "Computerized behavioral therapy device for psychiatric disorders." These initially were set to include digital therapeutics for insomnia, substance use disorder, depression and anxiety: Reset, Reset-O, SleepioRx, DaylightRx, Rejoyn and possibly, MamaLiftRx.

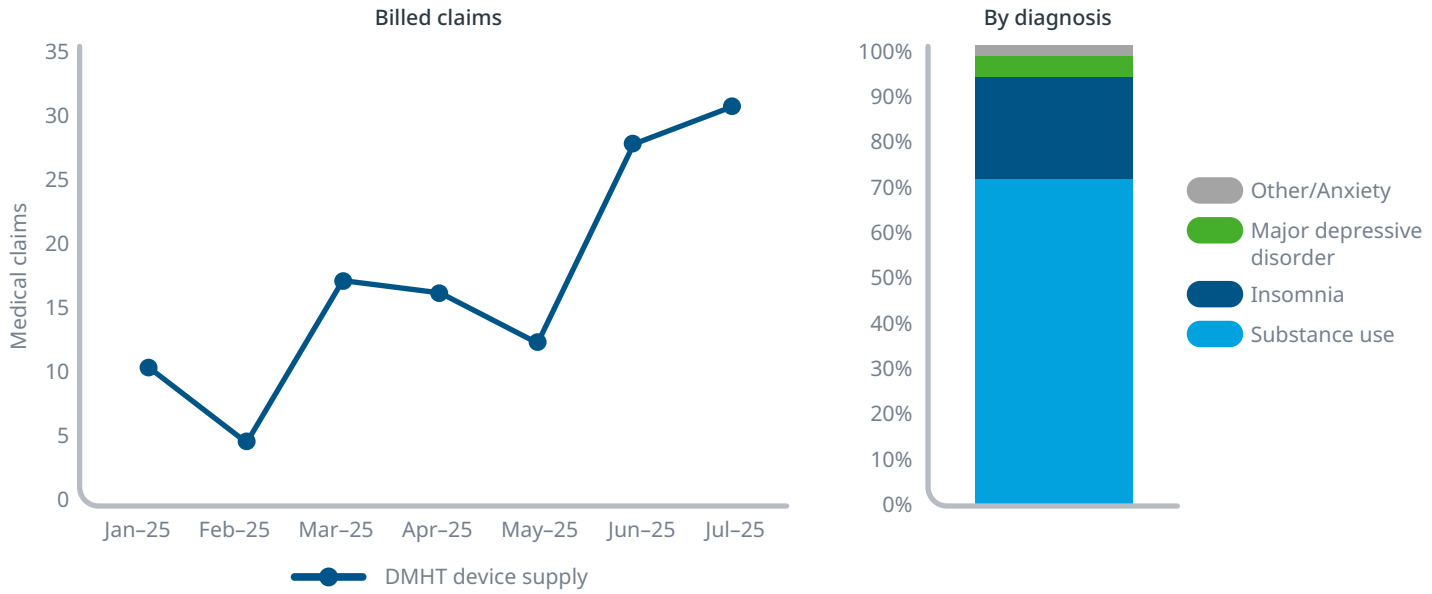
Since a qualified practitioner can be reimbursed when they purchase a device and then furnish it to a patient as part of a behavioral health treatment plan (and manage their treatment), these G-codes notably create emerging opportunities for care providers to "buy and bill" for the devices.[176,177] It also creates opportunities for DTx manufacturers to request

coverage from payers beyond Medicare (such as commercial payers and State Medicaid).[178]

The fact that Medicare made both the supply codes for digital tools and their associated services payable under Medicare is likely to position the Incident-to Pathway as the main route through which digital therapeutics gain reimbursement — both within traditional and virtual care settings in the U.S. So far, however, billing for DMHTs has remained limited although claims are growing, with products for substance abuse (likely Reset-O) and insomnia (likely Sleepio) leading early adoption (Exhibit 26).

> *"We are… proposing Medicare payment for digital mental health treatment devices furnished incident to or integral to professional behavioral health services."* [176]
>
> *— CMS 2025 Medicare Physician Fee Schedule Proposed Rule*

Exhibit 26: Use of digital mental health treatment devices (*based on a sample of medical claims*)



Source: IQVIA Institute Digital Health Billing Code Database, Sept 2025; IQVIA Medical Claims Data extracted Sept 1, 2025. Right chart: IQVIA Medical Claims Data extracted Aug 18, 2025.

Notes: Displays data for the device supply code G0552 only. Trend should be considered directional as distinct market dynamics mean data capture is currently unknown. Supply code as of Sept 1 2025 n=146; Adjustment disorder mapped to insomnia. MCI mapped to insomnia. OCD mapped to other Anxiety. Anxiety disorders likely reflect comorbid depression.

> *"The 2025 Medicare Physician Fee Schedule proposed rule … establishes a promising pathway to scale access to SleepioRx, and similar digital therapeutics that are deployed in clinical practice and can help address the significant unmet mental health need nation-wide."* [179]
>
> *— Big Health*

> *"Medicare FFS claims data for [DMHTs]... have remained low in volume since we established these codes in the CY 2025 PFS final rule. We understand there may be several reasons for this [including]..that the billing practitioner is incurring the cost of furnishing the DMHT device to the patient...[which] may not align with direct-to-consumer delivery and payment models that existed..."* [178]
>
> *— CMS 2026 Medicare Physician Fee Schedule Proposed Rule*

The slow growth in adoption is partly due to the way the supply of DMHTs are reimbursed under the new system. While CMS assigned fixed reimbursement amounts for clinical services using DMHTs, the agency felt it could not "appropriately price all the DMHT devices" and therefore made reimbursement for the supply of these products subject to contractor pricing.[178] This means the rate of payment is determined on a regional basis by Medicare Administrative Contractors (MACs) and can therefore vary by geography and also potentially by product.

As of September, DMHTs claims were billed at an average rate of $885 and currently range from $120 to $1000 (Exhibit 27). While it is possible commercial payers may reimburse at these rates, Medicare contractors in sample geographies listed reimbursement amounts of $51.55 and $128.87 for the supply of DMHTs, suggesting the reimbursed rates are likely to be much lower than list price, and therefore only partially cover the costs a provider might incur.[180] Still, even with partial reimbursement, providers may still be more willing to buy DTx under licensing arrangements with the knowledge that they can "buy and bill" for the tools themselves via medical benefit, or acquire them and bill for their use within digital care — as PursueCare has done with RESET and RESET-O. Participation by digital care providers can also offer an avenue to generate evidence of their device's efficacy in practice with some cost offsets. This data can then help manufacturers negotiate directly with the MACs or with CMS for per-product pricing.

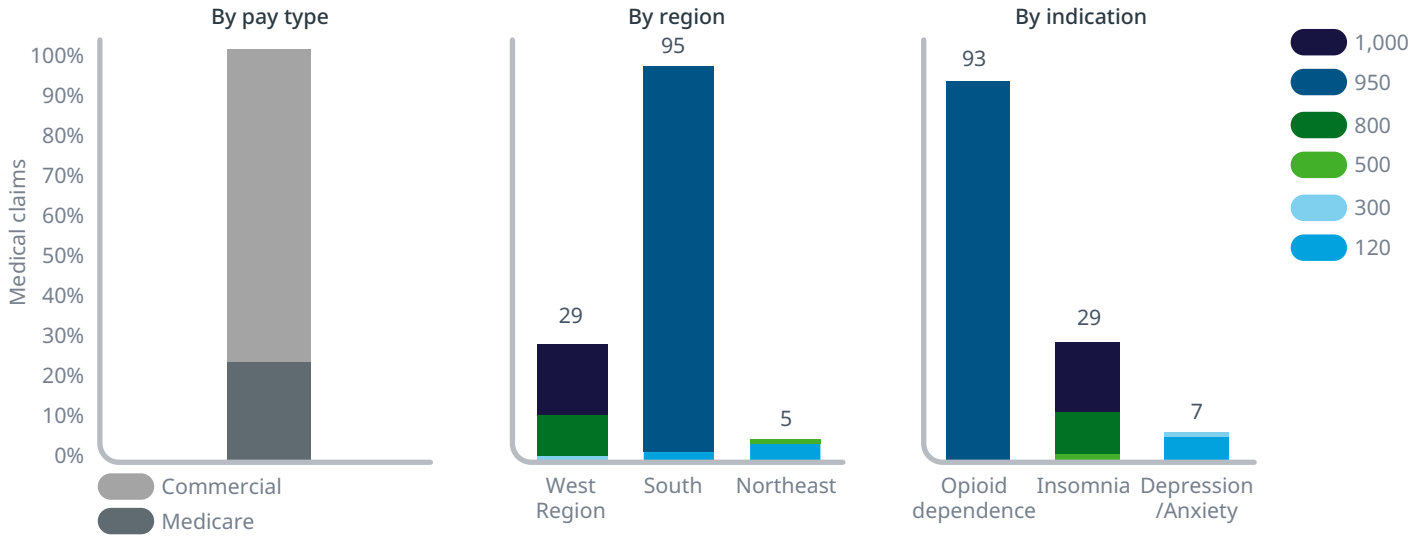
Meanwhile, reimbursement is currently standardized for all mental health DTx because the new contractor-priced codes were tied a specific FDA classification. As CMS discusses the potential to create similar codes for other types of SaMD, a product's regulatory submission and classification may — at least in the short term — become an important determinant of its initial pricing. This loosely parallels the way the DIGA pathway has set maximum pricing per therapeutic area, albeit at a more granular level.

Additionally, in the near term, because only approved prescription digital therapeutics (PDTs) can access this new revenue stream, developers may be incentivized to pursue FDA approval for their products — raising the bar on product safety and evidence. The lack of reimbursement pathways for self-guided non-prescription digital therapeutics (NDTs) and wellness products may already be influencing business decisions. For example, the Swedish pharmaceutical company Orexo recently ended its partnership to commercialize GAIA's Deprexis in the U.S. — a digital program for depression — citing the need for reimbursement and noting that, as an NDT, Deprexis would require additional investment to meet CMS's technical and regulatory requirements.[181]

Legislative and policy proposals

Further CMS rulemaking and new billing codes may continue to expand both use and coverage of digital

Exhibit 27: Billed amounts for digital mental health treatment devices (*based on a sample of medical claims*)



Listed reimbursement amounts

Medicare Administrative Contractor (MAC) fee schedules, 2025		
Contractor	In-network	Max
Novitas (C01, TX9)	$128.87	$140.79
Noridian (CA5, CA64)	$51.55	$56.32

Source: IQVIA Institute, Aug 2025; IQVIA Medical Claims Data, data extracted Aug 18, 2025. Published contractor price lists as of Jan 1, 2025.

Notes: Displays data for the device supply code G0552 only. Trend should be considered directional as distinct market dynamics mean data capture is currently unknown. Supply code n=131 with two outlier claims removed. Uses patient region.

> *"The technologies and DMHT therapies are evolving rapidly…[and] our payment policy, too, will evolve. Given the dynamic nature of the development of these devices and the variation in methods of action for potential technology platforms, we do not have sufficient information needed to establish national pricing for devices described by HCPCS code G0552 at this time…[but] continue to welcome information and may consider national pricing through future rulemaking."* [178]
>
> *— CMS 2026 Medicare Physician Fee Schedule Proposed Rule*

tools, alongside policy proposals from Congress. CMS has announced that DMHTs will be expanded to include ADHD tools in 2026 (such as EndeavorRx), and has invited input on adding categories for FDA-approved digital therapeutics targeting gastrointestinal conditions, psychiatric sleep disturbances, fibromyalgia, or biofeedback… which could potentially be created as similar buy-and-bill-type G-codes. These additions could potentially help cover products such as Nightware, Stanza, and Prism for PTSD, among others.

Based on discussions in the CMS 2026 Medicare Physician Fee Schedule Proposed Rule, the agency also appears poised to broaden the set of codes available

to bill for digital health tools used within care in the future to include ones that support lifestyle-based interventions and chronic disease management. In line with CMS's broader push to shift the healthcare paradigm toward prevention and wellness — and aligned with policy goals under the "Make America Healthy Again" (MAHA) initiative to address the root causes of chronic disease[182] — CMS invited public comment on establishing codes and payment for digital tools that "maintain or encourage a healthy lifestyle as part of a mental health treatment plan of care. These could potentially accommodate NDT-type wellness and disease self-management apps. The agency also discussed adding codes for digital therapeutics that treat or manage chronic disease symptoms.[178]

Separately, the proposed Medical Nutrition Therapy Act, aims to extend coverage of Medical Nutrition Therapy (MNT) to all Medicare beneficiaries and broaden eligibility to include additional conditions and disease states. In theory, this could also prompt CMS to introduce new billing codes for digital tools that promote nutrition, weight management for obesity, or support Food as Medicine (FaM) services. Such codes would not only expand reimbursement pathways but also accelerate the integration of digital health into preventive care models.

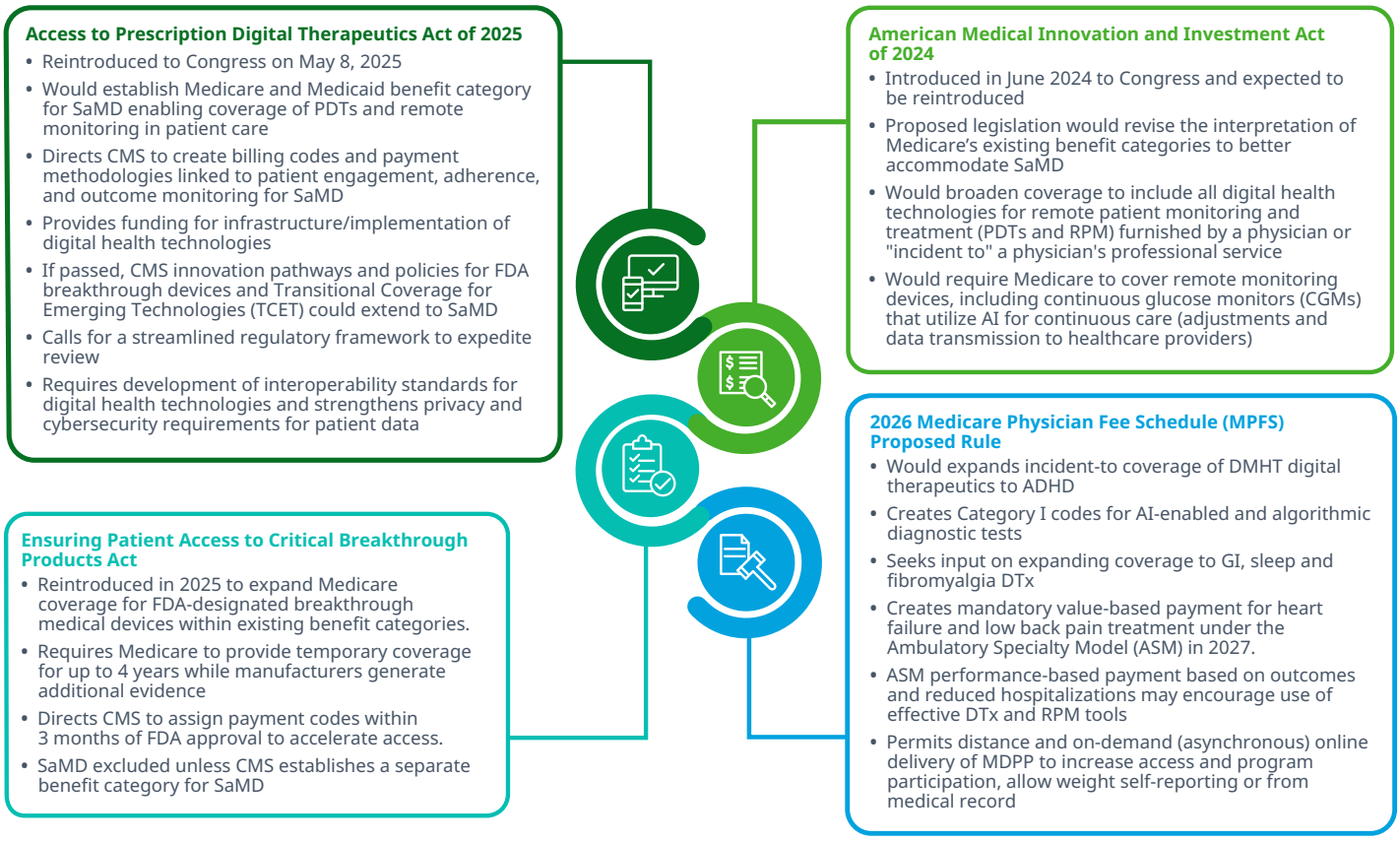
Other pending legislation seeks to formally establish Medicare coverage for SaMD, which currently lacks a defined benefit category (Exhibit 28). The Access to Prescription Digital Therapeutics Act (APDTA), which was reintroduced in 2025 (as H.R.3288/S.1702) would establish a distinct benefit category for SaMD, while the American Medical Innovation and Investment Act of 2024 (H.R.8816), would revise the interpretation of existing benefit categories to better accommodate SaMD.[184–186] However, the latter expired and has not yet been reintroduced. If either successfully passes, they could facilitate coverage for innovative SaMD breakthrough devices under the current Transitional Coverage for Emerging Technologies (TCET) pathway, launched by CMS in August 2024, or if the Ensuring Patient Access to Critical Breakthrough Products Act is enacted, enable temporary coverage for SaMD products with FDA breakthrough designation. However, the future of these bills remains uncertain, and operational barriers may persist even if they are enacted.

Care efficiency programs and value-based care

Finally, Medicare's goal of fully transitioning all beneficiaries to value-based care models by 2030 (rather than fee-for-service arrangements) is likely to create a more receptive environment for digital-first care providers. CMS's 2025 updates and the proposed 2026 Medicare Physician Fee Schedule reflect a clear shift toward outcomes-focused, efficient and coordinated team-based care, that integrates behavioral health care and can be delivered in a virtual format supported by digital tools.[187] Recent and proposed rule changes

> *"Now before Congress, Medical Nutrition Therapy Act could be a game-changer for FaM [Food as Medicine]. If passed, this law would enable all Medicare beneficiaries to receive MNT as a covered service… [and] expand Medicare coverage for MNT to additional conditions and disease states….Digital health companies are uniquely positioned to offer scalable, tech-enabled solutions in the FaM space."* [183]
>
> *— Nixon Law Group*

Exhibit 28: U.S. policy proposals addressing digital health reimbursement challenges



Source: IQVIA Institute, Nov 2025; Policy documents including H.R.8816; H.R.3288, S.5238.

Notes: Centers for Medicare & Medicaid Services (CMS); Prescription digital therapeutics (PDTs); Software as a Medical device (SaMD), Gastrointestinal (GI).

— from new bundled payment models and quality incentives to expanded telehealth and billing codes for digital therapeutics — signal strong support for integrating digital health solutions into care delivery.

Disease prevention and management program

Initially, the key route for digital care providers to serve public payers were disease management programs where distance learning or telehealth delivery were permitted. These include the Medicare Diabetes Prevention Program (MDPP), which offers performance-based payments for preventive care involving coaching, peer support, and lifestyle interventions, as well as Medicaid-funded case management services for substance use. Omada Health, for instance has been a CDC-recognized DPP supplier since 2018, exemplifying how digital platforms can scale diabetes prevention and chronic disease management through virtual coaching and behavior change.[188] CMS data also show that virtual MDPP delivery has been effective — with participants in distance learning programs achieving greater average weight loss than those attending in-person sessions.

The success of virtual delivery has led CMS to recently extend the virtual format of its Diabetes Prevention Programs and permit MDPP services online (including asynchronous/on-demand sessions) through 2029. Also, virtual-only organizations will be allowed to enroll as MDPP suppliers since the requirement to maintain in-person delivery capability was removed and participants will be allowed to self-report weight measurements as part of a medical record.

> *"After the PHE went into effect in March 2020, more than 90 percent of all MDPP sessions were delivered virtually via Distance learning.... Among beneficiaries that attend their sessions primarily in person, the average weight loss was 4.6 percent, compared with an average weight loss of 5.3 percent among those that attend sessions virtually via Distance learning."* [178]
>
> *— CMS 2026 Medicare Physician Fee Schedule Proposed Rule*

Value based payment

Although some employer-sponsored plans have already negotiated payment arrangements with partial outcome-based pricing, at the federal level, CMS leads value-based care reform by through risk-adjusted bundled payments and performance-based incentives that hold providers accountable for quality and total cost of care. Adding to CMS' longtime value-based payment programs like Accountable Care Organizations (ACOs) and the Kidney Care Choices (KCC) Model for end stage renal disease care, new "hybrid" bundled specialty models like the mandatory Ambulatory Specialty Model (ASM) for heart failure and low back pain have been announced (launching in 2027). Digital platforms supporting remote monitoring, education, and behavior change are increasingly integrated into these models.[189]

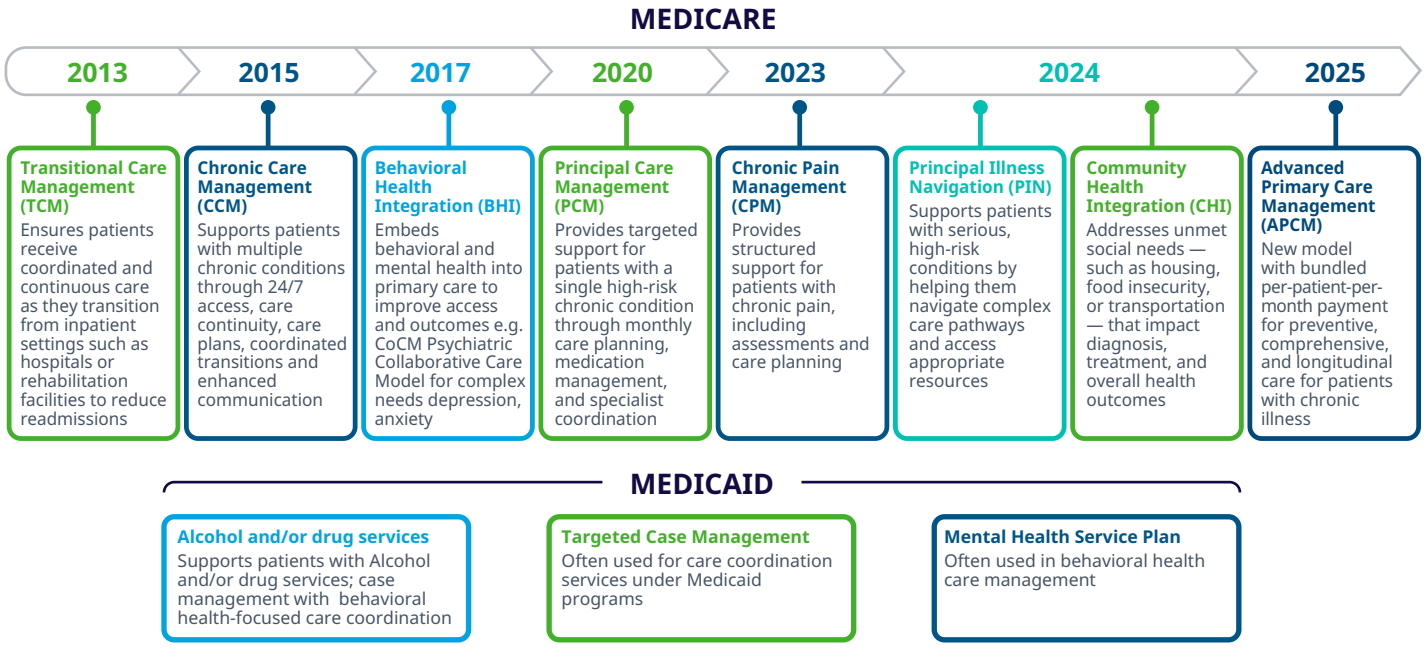
For instance, virtual solutions that can support the KCC model are currently being assessed by the Peterson Health Technology Institute, such as wearables and telemonitoring solutions for disease monitoring (e.g., of vital signs, treatment adherence, or physical activity), apps supporting education and behavior change, and digital platforms for CKD self-management. For the newer ASM back pain model, musculoskeletal therapy platforms similar to Hinge Health — which may combine virtual physical therapy, digital therapies, remote monitoring, and coaching—may be well-positioned to help orthopedists and pain specialists meet quality benchmarks and avoid unnecessary surgeries because they often already track outcomes and progress.

Digital platforms that support remote monitoring, asynchronous communication, and predictive analytics are increasingly valuable in these models to allow for proactive management. They identify high-risk patients and can reduce hospitalizations and improve adherence — key metrics in ACO and bundled payment performance. This is because value-based payment models rewards specialists who use technology to catch problems early, improve function, and share data electronically with patients and primary care. Telemonitoring tools and apps that collect patient-reported outcome measures (PROMs) may also help meet quality targets and facilitate reporting under Merit-based Incentive Payment System (MIPS) and the Medicare Shared Savings Program (MSSP). Virtual providers' reduced reliance on facility-based care may also lower costs while maintaining quality.

Care management and team-based care

Team-based care models where providers coordinate across primary care, specialty, hospital, and post-acute settings are central to CMS's 2030 value-based care goal. Over time, CMS has continued to introduce new billing codes for care management — integrated care delivery models designed to improve outcomes through efficient, team-based management of patients with specific conditions (Exhibit 29).[190] With the recent expansion of behavioral health coverage through care management codes — and the creation of billing codes for digital mental health treatment devices (DMHTs) —Medicare is opening new opportunities for digital health companies to help address gaps in chronic disease and behavioral health care.

Exhibit 29: Team-based care management as an opportunity for digital care in Medicare and Medicaid



Source: IQVIA Institute, August 2025.

Notes: Exhibit shows the year the program was introduced.

"An "advanced primary care" approach…is supported by a team-based care structure and involves a restructuring of the primary care team, which includes the billing practitioner and the auxiliary personnel under their general supervision…. This restructuring creates several advantages for patients, and provides …methods for patients to communicate with their care team/practitioner about their care outside of in-person visits (for example, virtual, asynchronous interactions, such as online chat), which can lead to more timely and efficient identification of, and responses to, health care needs." [191]

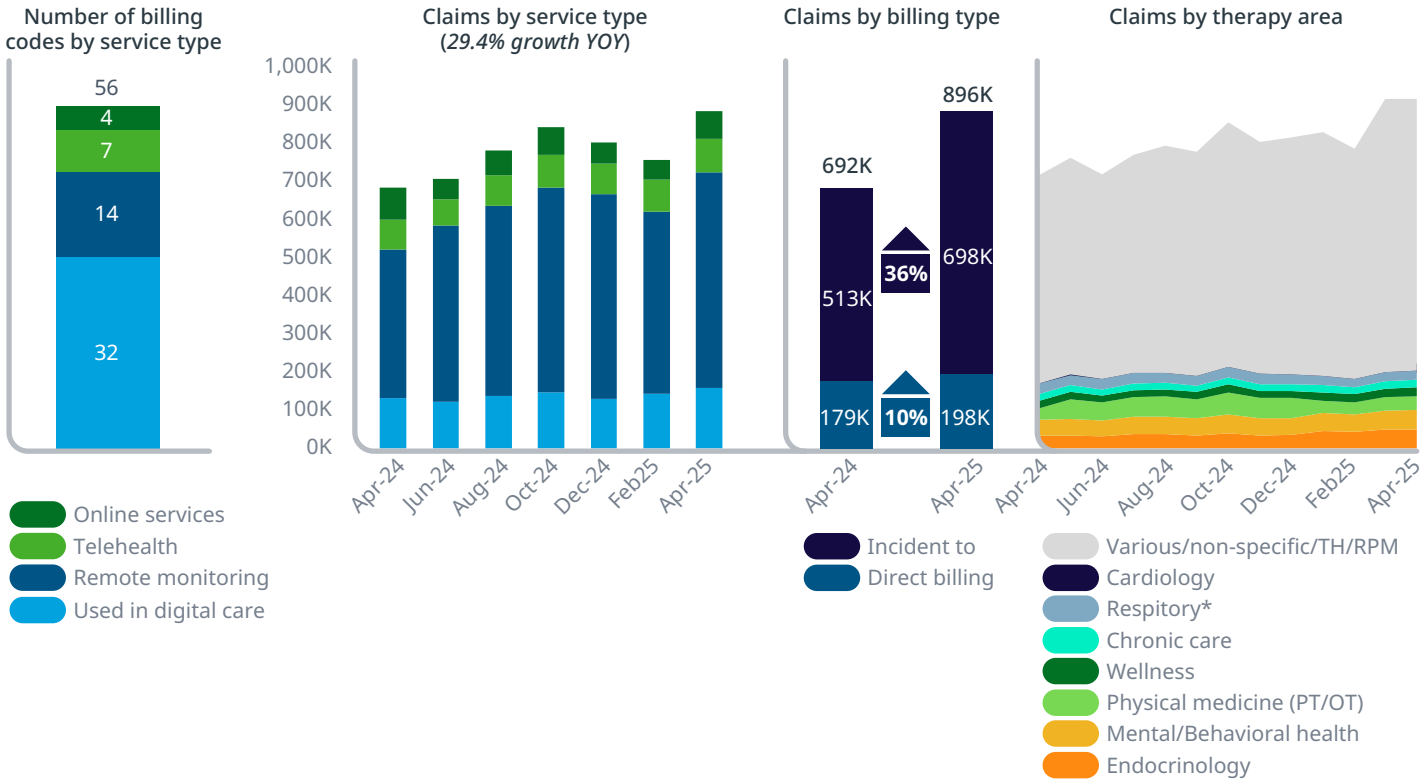
— CMS 2025 Medicare Physician Fee Schedule Final Rule

Although most of these payment models remain fee-for-service and are not tied to outcomes, quality benchmarks or shared financial risk like value-based care, they do promote operational efficiency and drive outcomes, making it easier to potentially shift care to value-based models by 2030 that reward performance. Among them, the Advanced Primary Care Management (APCM) model for patients with chronic illness, introduced in 2025, supports this shift by bundling multiple care management services into a flat monthly payment based on patient complexity. Although not yet tied to full financial risk, these models promote operational efficiency and ease the transition to value-based arrangements. Additionally, the integration of behavioral health services into many of these various collaborative care models and the fixed per-beneficiary payments may incentivize providers to adopt digital tools.[187,190,191]

To facilitate efficiencies with these models, care management codes allow typically allow for both virtual care delivery and "incident-to" billing by non-physician providers (e.g., clinical staff or auxiliary personnel like nurses, social workers, therapists, health coaches, dietitians) — where services they perform under general supervision can then billed under the provider's (or supplier's) NPI at higher Medicare reimbursement rates.[192–194] Making these codes eligible for telehealth and non-provider billing in a team environment substantially lower barriers for digital care providers, who often already used similar models. Digital health tools that support care in these arrangements, however, may not be directly reimbursed.

Although these new models are actively expanding incident-to billing to include more services and provider types, currently around 56 codes appear to be used most

Exhibit 30: Incident-to and non-provider billing codes and medical claims



Source: IQVIA Institute Digital Health Billing Code Database; Sept 2025; IQVIA Medical Claims Data, data extracted Sep 21, 2025.

Notes: Incident-to and non-provider billing codes trended here include only those commonly used in digital care. Displays the telehealth value for only for general provider codes not already specific to telehealth but leaves device-enabled services like remote monitoring unmodified. A flat telehealth percentage of care was calculated per code based on Q12025 telehealth data and applied across time. Excludes codes with variable payer policies pertaining to incident billing.

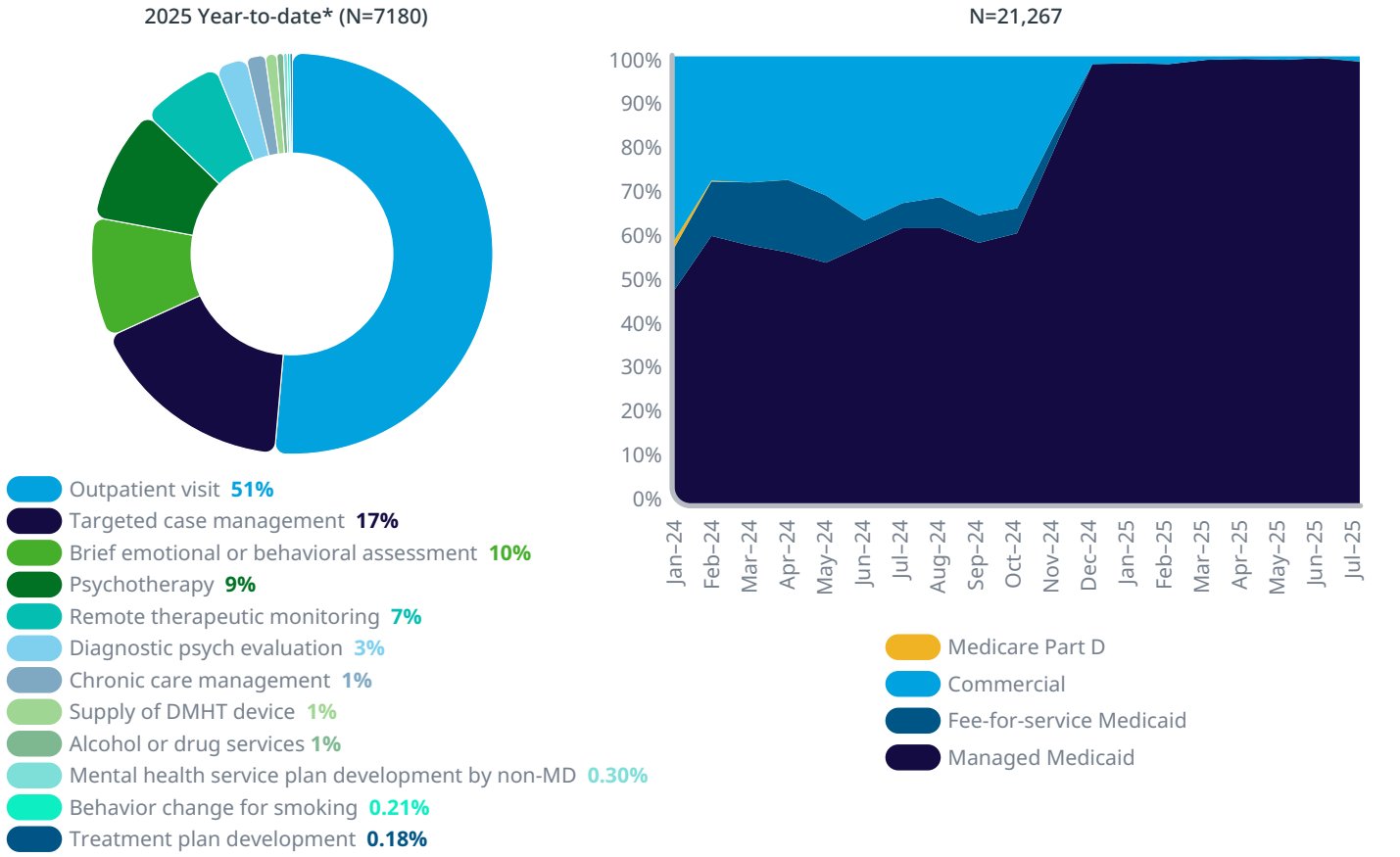
actively in digital care that facilitate incident-to billing or direct billing by non-physician providers (with the latter typically billed at lower rates). These include services relating to online e-visits, remote monitoring (RPM/RTM), physical rehabilitation, therapeutic training exercise, and disease management programs, From April 2024 to April 2025, incident-to billing claims grew by 36%, compared to only 10% growth for services billed directly by non-physician staff (Exhibit 30). This suggests that there has already been robust growth in team-based models of care and care delivery using incident-to codes.

Digital providers such as Omada Health, Teladoc, PursueCare, and Hinge Health are well-positioned to support these evolving value-driven models. PursueCare, for example, which focuses on virtual addiction treatment and mental health stands to benefit from Medicare's efforts to integrate behavioral health into primary care and expand coverage for digital mental health tools. In short, as Medicare moves away from fee-for-service and towards care coordination, prevention, and accountability, digital health companies may find opportunities to scale within the public health ecosystem.

Medicaid

PursueCare, for instance, has already had some success in delivering behavioral health counseling for Medication-Assisted Treatment (MAT) through Managed Medicaid (Exhibit 31). While Medicaid is jointly funded and administered by federal and state governments, reimbursement is decided at the state level unless CMS mandates coverage of a specific product type

Exhibit 31: Medical claims billed by a digital care provider treating substance abuse by service and pay type



Source: IQVIA Institute, Jul 2025; IQVIA Medical Claims Data, data extracted Jul 19, 2025.

Notes: Trend should be considered directional as distinct market dynamics mean data capture is currently unknown. *Includes Jan 2024-May 2025 full data and partial data from June-July. Managed Medicaid includes Medicare Supplement, Medigap, State Assistance.

or application in the federal register. However, most states Medicaid plans cover behavioral health services pertaining to mental health and substance use treatment, making Medicaid the largest payer for substance use disorder (SUD) services in the U.S. Many dual-eligible beneficiaries (people on both Medicare and Medicaid) also receive coordinated SUD care through integrated plans.

Until recently, mobile apps and digital tools were not able to bill separately within case management arrangements, making it essential for these tools to offer improved outcomes or care efficiency. However, with CMS' creation of supply codes to bill for DMHTs, digital therapeutics are now partially reimbursable and are being used within PursueCare's model.

Medicaid policies in 2025 also support telehealth delivery of case management for mental health and SUD populations. For instance, recent changes to the Four Walls Requirement allow states to cover telehealth behavioral health clinic services from any location, including the patient's home, through 2026. This includes mandatory coverage for Indian Health Service (IHS) and Tribal facilities, expanding access to virtual care.[195,196] Some states have also made telehealth flexibilities permanent.

Other prescription digital therapeutics and even digital diagnostics have been successful in securing reimbursement under State Medicaid, which then include them on preferred drug lists, although Medicaid coverage remains limited. For instance, Cognoa's autism diagnostic tool, Canvas Dx, is covered by some Medicaid, such as Medicaid in Wyoming and is participating in early start programs in Arizona and California.[197] Medicaid Demonstration Waivers also offer additional opportunities for digital therapeutics to introduce their products into Medicaid programs if they are cost-neutral, allowing states to pilot innovative services outside standard rules.

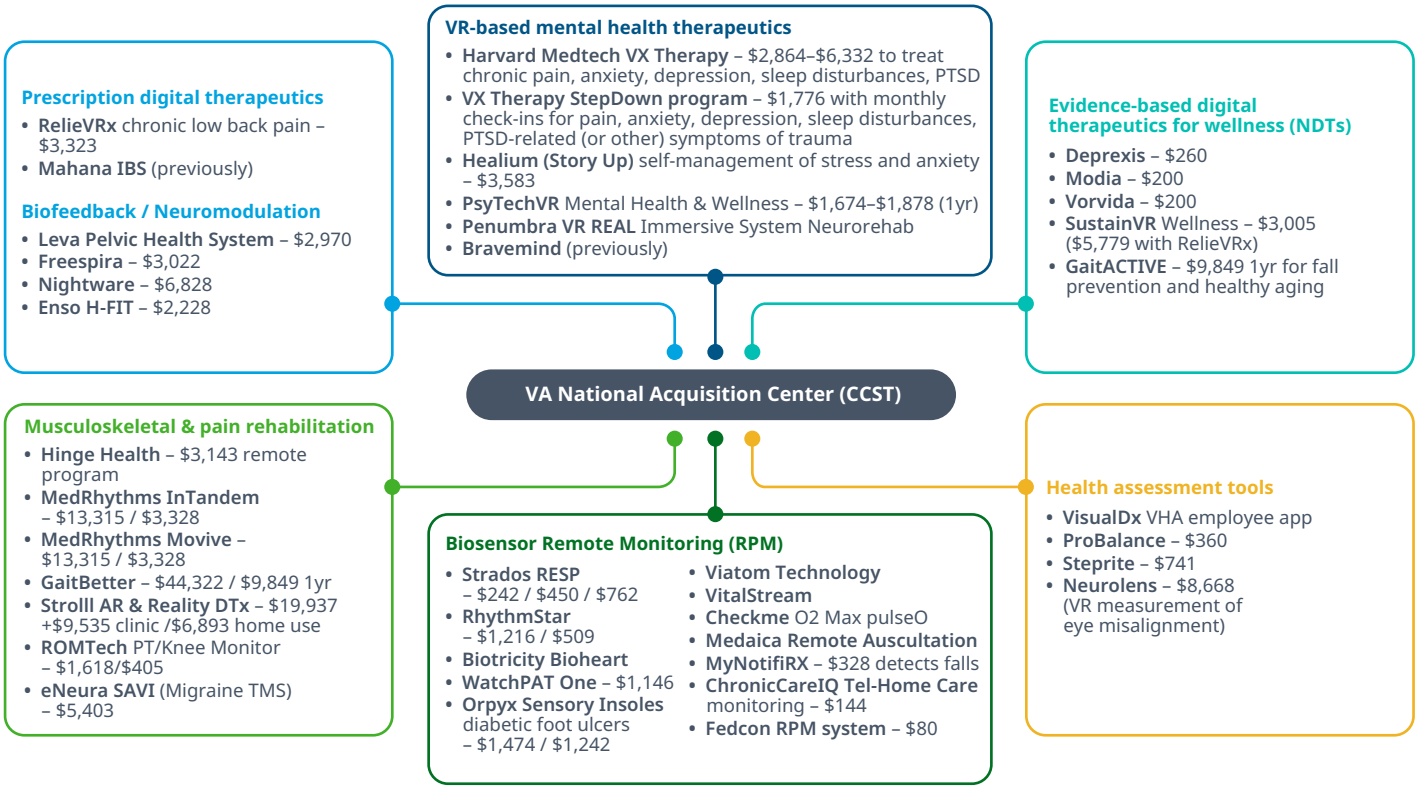
Federal Healthcare Agencies

Finally, in the United States, federal healthcare providers — including the Department of Veterans Affairs (VA), the Military Health System (MHS) under the Department of Defense (DoD), and the Indian Health Service (IHS) — provide care for active duty service members, veterans, and eligible family members. These agencies have adopted digital tools to improve access and outcomes, especially in remote areas and deliver care to distant geographies. They have integrated digital tools into care by running pilot studies and through federal procurement mechanisms: most notably the VA Federal Supply Schedule (FSS) and DoD mechanisms such as Distribution and Pricing Agreement (DAPA) and Defense Logistics Agency (DLA) Electronic Catalog (ECAT) program. These vehicles allow federal facilities to acquire commercial products and services at pre-negotiated prices.[198]

This channel can be a viable early adoption route for products that align with federal care priorities and can demonstrate benefit in veteran and military populations. The U.S. Department of Veterans Affairs (VA) has taken a lead in testing and scaling digital therapies and other digital tools in a care setting with staff running pilots immersive and digital tools and the VA National Acquisition Center (NAC) contracting with devices manufacturers and their distributors for listing on the FSS catalog after a review process that includes contractor past performance, financial stability, and commercial sales practices. The VA may also help manufacturers to scale up within the health system if companies can demonstrate their product can benefit veterans.

Various digital health devices have been listed on the FSS including ones using virtual reality (VR) for physical rehabilitation and neurorehabilitation, DTx for pain and mental health (targeting depression, PTSD and substance abuse) and stroke-related walking impairments, as well as evidence-based wellness products (NDTs) and remote monitoring tools for chronic conditions (Exhibit 32).

Exhibit 32: Digital health solutions with federal contracts



Source: IQVIA Institute; Aug 2025. The VA National Acquisition Center (NAC) Contract Catalog Search Tool (CCST) [Accessed August 2025]. Available from: https://www.va.gov/library/mobile.asp

Devices using VR for rehabilitation appear to have made inroads gaining reimbursement. According to VA's own program page, more than 3,500 VR headsets are now deployed across more than 170 VA medical centers and outpatient clinics in all U.S. states and territories to ensure veterans can receive needed care from any location and support use cases spanning creative art therapies, physical rehabilitation, management of phantom limb pain, mental health therapies to help decrease pain, stress, anxiety, boredom, and restless behaviors.[199] A 2023 Veteran's Affairs guide to immersive technologies mentioned the use of at least 21 extended reality (VR/AR) Software platform technologies. Reimbursement ranges from $200–$260 for NDTs and up to $3,300 for DME-based digital therapeutics like VR, and $2,000 for maintenance-stage versions of those digital therapies.

Several digital therapeutics (especially DME and VR-based ones) have been listed for use and reimbursement and were among the earliest to be adopted by the VA including Bravemind, Nightware (distributed through grants/donations and research channels), Freespira to treat soldiers with PTSD, and MedRhythms' InTandem for veterans with stroke-related walking impairment.[203] Pure software-based apps like Deprexis have been reimbursable under the FSS since July 2022, and Mahana IBS, Modia and Vorvida were later listed.[199–204] The three products that remain available are now paid at a rate of $260 or $200 as of May 2025.[200] These and many more examples demonstrate how government agencies have become increasing comfort with these innovative approaches.

Notably, the VA appears to have contracted for solutions where the manufacturer offers tiered levels of care such as a clinical therapy tool alongside a wellness offering that can support a maintenance phase of care including RelieVRx and SustainVR, VX Therapy and its corresponding StepDown program, and GaitBetter alongside GaitACTIVE.

Global reimbursement opportunities

+ **Policymakers have expanded funding for innovative digital health technologies as they compete to attract these solutions to their markets. Japan now offers price incentives for early market entry, while the UK plans rules-based funding of NICE-recommended solutions starting in 2026.**
+ **Initial enthusiasm by public insurers to support digital therapeutics in Europe and Asia has been tempered by pragmatic approaches aimed at managing long-term costs: aligning pricing with delivered value, adjusting prices dynamically as evidence grows, and in some countries, paying only low rates until developers prove product value.**
+ **Prices of reimbursed digital health applications are now modified based on demonstrated real-world outcomes and patient engagement metrics proving active use, while volume-based pricing ensures costs health system costs decrease as market competition increases.**
+ **Temporary reimbursement provided during the evidence generation, has been anchored to the negotiated prices of comparable products in Germany, reference products in France, and to product development costs in Korea, but in the U.S. and elsewhere billing codes mostly facilitate optional contracting with private payers.**
+ **Although some countries reimburse the cost of software-based devices directly, others have taken an approach to pay for an integrated care pathway that incorporates digital tools.**
+ **The time to revenue for prescription digital therapeutics varies across markets — ranging from 2.5 years in Germany to ten years elsewhere — but may be accelerating as companies launch their second and third products.**

National reimbursement policies are continuing to evolve worldwide as policymakers seek to strike a balance between the benefits and costs of innovative digital health technologies that offer to optimize care. Policymakers have been creating new revenue incentives to attract developers to their markets early, while simultaneously taking steps to link the prices of digital health tools to their demonstrated value and that of comparable products, limit reimbursement during the evidence generation period, and ensure prices decrease over time as competition increases.

NEW FUNDING FOR INNOVATION

A pathway to funding in the UK

In the UK, where national reimbursement for digital solutions has been lacking, a rules-based funding pathway is expected to launch in 2026. For promising, cost-efficient solutions recommended for NHS use via NICE's HealthTech Guidance, the new pathway aims to guarantee development funding for emerging digital health solutions and facilitate national commissioning as their evidence-base grows — parallel to what is already available to drugs. A HealthStore is also planned to enable patients to more easily obtain apps.

> *"Unlike for medicines, there is no national pathway to prioritise and nationally fund the highest impact HealthTech. As a result, we see significant unwarranted variation in uptake, weakening the perceived attractiveness of the UK market."* [50]
>
> *— Fit for the Future 10 Year Health Plan for England.*

Until recently, reimbursement decisions for digital health solutions in the UK were made predominantly by regional Integrated Care Boards (ICBs), which manage the budgets and contracts for the 42 Integrated Care Systems (ICSs).[205,206] Manufacturers might gain permission to pilot their technologies at NHS facilities in one or more regions — sometimes as part of NHS evidence-generation initiatives — and if local technology assessments were favorable, ICBs would make ad-hoc decisions whether to make them available to their local populations. This led to inconsistent access and has limited the ability for digital health solutions to scale.

Although the creation of NICE "Early Value Assessments" (EVA) in June 2022 provided a route to receive initial recommendation for use "in practice" within the NHS and reduced barriers to adoption by local commissioners, recommendation was not paired with automatic funding.[116] Developers could apply for temporary funding through the Invention for Innovation (i4i) programme to support use and evidence generation within the NHS, but only via a competitive process requiring business case approval and the creation of a real-world evidence generation consortium (of NHS sites, product providers, and analytical partners).[207,208]

Even for mature solutions that received full NICE recommendation, national reimbursement remained elusive. These include products recommended under Medical Technology Guidance (MTG) or Diagnostic Guidance (DG), such as KardiaMobile 6L and Zio XT for arrhythmia detection, Sleepio DTx for insomnia, GaitSmart's rehabilitation programme, and others to detect sleep apnea and monitor Parkinson's disease. NICE recommended the use of these products by the NHS but ultimately, funding decisions were still left to ICBs or individual NHS Trusts.

For example, Sleepio — the first digital therapeutic to gain full recommendation for use via MTG in 2022 — was recommended as a first-line therapy before sleeping medication and demonstrated cost-saving potential, but is still not nationally reimbursed in England despite [see Callout].[209–212] In contrast, NHS Scotland decided to provide national access to Sleepio and Daylight for the entire Scottish population in October 2021, as well as free access to another solution, SilverCloud.[213,214]

However, the NHS took initial steps from 2022–2023 to accelerate access to innovative technologies including digital health solutions through initiatives such as the MedTech Funding Mandate (MTFM) and the Innovative Devices Access Pathway (IDAP) pilots.

REIMBURSEMENT OF SLEEPIO

In May 2022, Sleepio became the first DTx to be recommended for reimbursement by NICE MTG guidance, even being put forth as a first-line therapy before sleeping medication.[209] Sleepio presented robust evidence including 28 studies — 12 of which were randomized controlled trials — and met ESF's key requirement to demonstrate benefit in the UK population through seven UK studies and four multinational studies.[215] However, the absence of a funding mandate for digital health technologies has meant that individual regional Integrated Care Boards (ICBs) ultimately decide whether to cover the solution. As a result, Sleepio continues to be covered by select parts of the NHS in England,[209] some of which took part in pilots to develop the evidence presented to NICE. For example, the Oxford Health NHS Foundation Trust took part in the pilot of Sleepio for young people[216] and now provides it for free to NHS patients in the Thames Valley.[211] While NICE considered Sleepio to save costs after one year at a proposed price of £45 per user, actual pricing is negotiated with NHS Trusts.

The MTFM mandated national access to medical devices that meet three criteria: effectiveness (based on NICE Diagnostic Guidance or Medical Technologies Guidance), net cost savings (demonstrated within three years), and affordability (annual cost not exceeding £20 million), however no digital health solutions were included. And the IDAP pilots — drawing inspiration from the pharmaceutical sector's Innovative Licensing and Access Pathway (ILAP) — aimed to inform the creation of a fast-tracked processes from regulation to reimbursement, offering multi-partner support, scientific advice.[217]

"From April 2026, building on and adapting our experience with medicines, we will begin expanding NICE's technology appraisal process, which includes mandated funding by the NHS, to cover some devices, diagnostics and digital products. This will focus on those that meet the NHS's most urgent needs and support financial sustainability… it will provide accelerated commercial support, enable quicker and simpler access to NHS infrastructure for evidence generation, and intensive adoption and pathway transformation support…" [50]

— Fit for The Future 10 Year Health Plan for England

These have both been used to inform the creation of a proposed structured and nationally funded "integrated NICE and NHS pathway" for health technology linked to the newly launched NICE HealthTech Programme pathway for devices, diagnostics, and digital tools.[218,219] The pathway would most critically tie funding to some NICE guidance in 2026.[218,220] For early promising technologies that address a national NHS need with plausible potential to offer value for money, the new Early-use HealthTech Guidance would conditionally recommend them for NHS use and make developmental funding available to them during evidence generation.[221] These would typically be technologies with "recent, ongoing or upcoming appropriate regulatory approval." Parallelling ILAP, for products already in use, the NHS would then "support the routine commissioning of technologies determined to be clinically and cost effective by NICE" and technologies with strong evidence will be surfaced through the NHS HealthStore, centrally procured, and funded from national budgets.[50,113,220]

"For those technologies that are recommended by NICE as clinically and cost-effective and that meet an NHS affordability test, there will be a commitment to automatic identification of funding to support routine commissioning, providing a clear incentive for industry to continue to invest in evidence generation and partnership with the health service and NICE." [218]

— NHS England proposal. 2024 May 22

"The first technologies to be surfaced through the HealthStore will be those that already have the best evidence of effectiveness following evaluations by NICE. These will be procured once by the NHS to secure a good price, with the costs borne from central budgets." [50]

— Fit for The Future 10 Year Health Plan for England

The new HealthTech program notably removed separate cost-effectiveness analyses from national assessments and shifts the focus to benefits for patients and services and overall value-for-money. This essentially gives local NHS offices more freedom to incorporate technology they feel valuable into practice. Guidance for health technologies can still use cost utility analysis and cost comparison for multiple technologies with the same purpose available to the NHS.[113]

Price incentives and provider reimbursement in Japan

In addition to new policies designed to accelerate the development and market entry of innovative software as a medical device (SaMD), such as digital therapeutics Japan has taken steps to speed the introduction of foreign-developed solutions. It has sought to attract international developers to its market by sweetening reimbursement amounts for products introduced to the Japanese market early and those demonstrating high clinical utility or innovation.[222]

Specifically, as part of the April 2024 healthcare reimbursement revision, the Ministry of Health, Labour and Welfare (MHLW) and its advisory body, the Central Social Insurance Medical Council (Chuikyo), introduced the 'Early Introduction' price premium that boosts the final National Health Insurance (NHI) product price by 5–10% to incentivize early launches of innovative therapies, including digital therapeutics in Japan. Unlike the earlier Sakigake premium, it is available to foreign manufacturers.[222] To qualify, developers must include Japan in the first wave of global product introductions — within six months of initial submission and approval in the U.S. or Europe — and conduct clinical trials in Japan ahead of or concurrently with other markets. Additional Clinical Value Incentives up to 70–120% were also made available for products with novel, clinically meaningful mechanisms of action, superior efficacy or safety compared to existing treatments, and other measurable improvements in care — such as new formulations and treatment of unmet needs, orphan, or pediatric populations.[222]

Japan has formalized a flexible reimbursement framework for prescription digital therapeutics (DTx), covering them as either a special treatment material (STM) — such as standalone medical devices with a listed insurance price — or as a medical service fee when integrated into standard care, or a hybrid of both.[223,224] Historically, Japan's reimbursement system separated product payments (for drugs and devices) from service fees (for physician activities and procedures), and rarely did a therapy receive both.

However, to support clinical integration, Japan introduced a new billing code for physician management of DTx: a monthly 90-point fee (¥900/~$6) for ongoing management and a one-time 50-point add-on (¥420/~$3) for initial app setup, acknowledging the time required to educate patients. This new system creates a hybrid model for medical devices used within treatment programs, combining official device reimbursement for the app with the monthly physician oversight fee, while patients cover 30% of the total cost. By reimbursing both the product and provider time, the framework makes

DTx adoption more attractive and feasible for clinicians, since they know they will not lose money or time when introducing a new digital therapy.

Among approved DTx products reimbursed under Japan's public insurance, coverage was typically granted 4–7 months post-MHLW approval.[138,225] CureApp SC was benchmarked to a standard 12-week treatment program and reimbursed at ¥24,000 (~$163).[226] CureApp HT is reimbursed at ~¥7,000 (~$56), while CureApp AUD (for alcohol use disorder) received ¥7,010 (~$47) coverage starting September 1, 2025, under the disease treatment program classification, and — to ensure value — reimbursement is tied to active patient engagement with the app recording their drinking records.[227–229] Susmed, which received approval for its Med CBT-I app for insomnia in February 2023, also recently resubmitted for reimbursement after reclassifying the app as a treatment support tool for insomnia ("Medcle")."[230–232]

Volume-based pricing in France

France's new national reimbursement pathways — PECAN and LATM — offer a more streamlined route to access for digital therapeutics and remote monitoring solutions. Notably, both pathways support early products by paying more per patient to early entrants through a degressive volume-based pricing mechanism where rates are reduced as the number of patients using solutions within the same class grow.

Prior to PECAN, digital therapeutics could only seek national reimbursement through the LPPR pathway like medical devices, which required submission to CNEDiMTS and robust evidence of clinical benefit. However, digital therapeutics found only limited success meeting these requirements and the few that did obtain reimbursement with limitations. For example, Moovecare received only a three-year reimbursement in 2019 — shorter than the standard five years for medical devices — and had to provide additional data demonstrating its benefit in the real-world for renewal. Deprexis was granted the full five-year term in 2022, but its use was restricted to mild depression, with CNEDiMTS similarly requesting real-world evidence to validate its safety and efficacy in the French population, and neither product remains reimbursed today.

Under PECAN, manufacturers can gain temporary reimbursement for one year (Exhibit 10), but the pathway sets high barriers to entry, requiring robust evidence and economic value submission to be filed soon after temporary reimbursement is approved. In practice this means confirmatory evidence of clinical benefit or care delivery improvements must be near-final and a positive result almost assured. So far, even with the shift to PECAN, no digital therapeutics have managed to gain temporary reimbursement to date, and at least five were rejected across indications: insomnia, erectile dysfunction, tinnitus and pediatric asthma.

In contrast, reimbursement opportunities have notably expanded for telemonitoring solutions under the PECAN and LATM pathways, which share the same billing structure and reimbursement codes, and these pathways are being used actively. Telemonitoring devices from more than 29 manufacturers have gained reimbursement across six application areas (Exhibit 33).

Under PECAN, reimbursement for digital therapeutics and telemonitoring products also differ. Digital therapeutics are reimbursed at initial flat rates of €435 per patient (which include the 20% VAT tax) covering treatment for the first 3 months, followed by monthly payment of €38.30–€780 maximum per patient per year with no prescriber reimbursement.[86,233] Under LATM, manufacturers receive between €20.83 to €91.67 per patient per month — a "technical package" for providing the device and telemonitoring care team performing data collection, analysis and any related reports and alerts with the exact price determined by the solution's proven organizational and clinical benefit the solution — and a maximum of €50 under PECAN. For instance, a solution with organizational interest may be paid only is €50 (see below) while solutions that demonstrate a mortality benefit can earn €91.67.

- **€50**: Organizational interest
- **€73.33**: Clinical interest (quality of life)
- **€82.50**: Clinical interest (morbidity)
- **€91.67**: Clinical interest (mortality)

Exhibit 33: Reimbursement in France under LATM and PECAN in early 2025

Respiratory	Nephrology	Cardiovascular	Diabetes	Cancer	Pain
RESPIRATORY FAILURE €50,00 MONTHLY Healabs Epoca Biosency Serviligne Srett Datamedcare MHCOMM Comunicare Generic/Other	**RENAL FAILURE** €47,03 MONTHLY Epoca Semeia Serviligne Healabs MHCOMM New Card Equasens Comunicare Predict4health Generic/Other	**CHRONIC HEART FAILURE** €40,20 MONTHLY Epoca Edevice Np Medical Implicity Be Ys Hs Fr Careline Healabs MHCOMM New Card Comunicare Predict4health Serviligne 1 Minute Pour Mon Cœur Generic/Other **€74,37 MONTHLY** Satelia Cardio **DEFIBRILLATOR/ PACEMAKER** €540,21 SEMI-ANNUALLY Abbott Microport Biotronik Boston €432,17 SEMI-ANNUALLY Medtronic Generic/Other €90,04 MONTHLY Implicity IM009 Generic/Other	**GESTATIONAL DIABETES** €50,00 MONTHLY Glooko XT MyDiabby **GESTATIONAL DIABETES ON INSULIN** €50,00 MONTHLY Medtronic Glooko Epoca Serviligne Comunicare Steto MDHC MHCOMM Generic/Other **DIABETES ON INSULIN** €48,79 MONTHLY Medtronic Epoca Serviligne MDHC Glooko MHCOMM Steto Comunicare Generic/Other	**LOCALIZED CANCER** €50,00 MONTHLY (€48,43 monthly CIM11 2C) Resilience Pro, Betterise (Originally PECAN) **ADVANCED METASTATIC CANCER** €73,33 MONTHLY (€70,20 monthly CIM11 2C) Resilience Pro Cureety (Originally PECAN) €50,00 MONTHLY (PECAN) Continuum+ Connect Adult patients with cancer undergoing systemic treatment	**LOW BACK PAIN** €50,00 MONTHLY (PECAN) Axomove Therapy Post inpatient rehabilitation

Source: IQVIA Institute, Apr 2025. L'Assurance Maladie. Liste des Produits et des Prestations. Available at: http://www.codage.ext.cnamts.fr/codif/tips//chapitre/index_chap.php?p_ref_menu_code=1718&p_site=AMELI

Notes: Includes Type 1 And Type 2 diabetes. Digital medical devices used for medical telemonitoring activities (DMN-TSM). None approved have been purely dispositifs médicaux numériques à visée thérapeutique.

However, these rates are subject to downward adjustment every six months based on the number of patients using any solution within the same class (i.e., the "active queue"), as part of a volume-based pricing mechanism. This means that, over time, reimbursement for organizational interest-only solutions may decline to €20.83 per patient per month, which is considered the floor rate. Already, reimbursement amounts have shifted from those initial amounts, with telemonitoring solutions for chronic heart failure at €40.20.[235] In addition, a fixed €28 "operators package" is paid to the prescribing healthcare professional, who is responsible for verifying patient adherence and compliance (i.e., data return >50%) at one and two months after the initial prescription.[234,235]

Further, manufacturers of telemedicine solutions can apply for reimbursement under an existing generic line created initially for chronic respiratory failure (such as COPD), diabetes, chronic heart failure, implantable cardiac devices, and renal failure or if their solution is similar to an existing product, or — if their solution

provides clinical or organizational benefits or is in a new category — they may file a de novo application for brand-name listing: Applying for a branded listing allows manufacturers to pursue higher reimbursement rates under its own line, as Resilience PRO did as the first solution to achieve permanent brand listing.[236] The new brand codes also create a pathway for other innovative products to seek higher reimbursement by claiming equivalence to an existing branded product — though success varies. For example, one applicant failed to prove equivalence to Resilience PRO, to be reimbursed under its rate, while Cureety later succeeded in doing so.

> *"The amounts reimbursed… for the MND [Dispositifs médicaux numériques] operating package, monthly and non-cumulative… may be adjusted according to the average monthly active file of all patients who have benefited from a medical telemonitoring activity in the same indication (all manufacturers included)."* [118]
>
> *— G_NIUS*

Care pathway reimbursement in Belgium

The Belgian system similarly provides a form of national reimbursement, however, rather than reimbursing digital health products directly, Mhealth Belgium statements indicate the goal is not to reimburse apps in isolation, but to reimburse care processes that incorporate patient-facing medical applications:

> *"The imposed insurance for medical care will in some cases integrate mobile medical applications into the healthcare system… into existing or new care processes if they offer a benefit or added value. The intention is not to reimburse applications per se, but their use within the context of a specific care process… gradually, more and more care processes and their financing will be adapted to today's needs and possibilities."* [237]
>
> *— Mhealth Belgium*

While any CE-marked solution can technically be used in Belgium, only those that reach M3 status through the mHealthBelgium pyramid are eligible for national reimbursement within a defined care pathway that defines staffing requirements and the scope of services provided. Hospitals can then enter into contractual agreements with INAMI/RIZIV to use digital solutions and be reimbursed. This model is intended to ensure that digital health solutions are only paid for when they are embedded in clinically meaningful pathways where they have proven to deliver measurable value, and when they are staffed appropriately.

However, unlike in Japan where device prices are specified, in Belgium hospitals receive bundled payments that include the cost of the app and associated services, and device costs are not carved out independently. For instance, under its first approved heart failure telemonitoring pathway launched in 2025,

hospitals receive €200 for the first month of remote monitoring, covering device provision (e.g., weight, blood pressure, or pulmonary pressure monitors), patient education, and initial consultations. This is followed by €90 per month for months 2–6, and €45 per month thereafter.[238]

COST MANAGEMENT APPROACHES

Value-based pricing in Germany

Even as Germany has expanded the types of digital tools that are reimbursable, it has taken deliberate steps to align the prices of emerging digital therapeutics with existing products in the same category and move towards performance-based pricing. Under the DiGA pathway, manufacturers were initially permitted to set their own prices during the one-year provisional listing phase, with costs billed to the GKV-Spitzenverband (GKV-SV), the umbrella body for public/statutory health insurers. However, concerns emerged over high initial prices — ranging from €784 to €2,077 — and inconsistent clinical value, prompting regulatory reform. Many were considered excessively high given that confirmatory evidence had not been produced and, ultimately, some DiGA fell short on delivering their expected benefit.

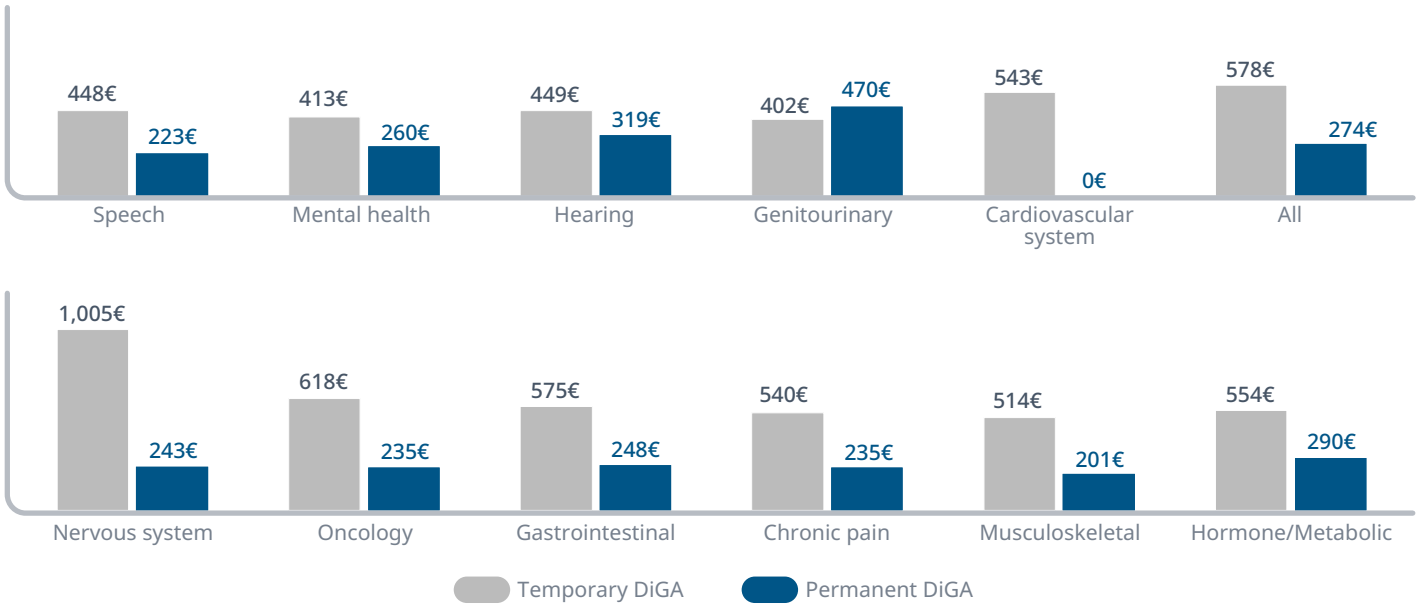
In February 2024, a joint agreement between GKV-SV and DiGA manufacturer associations introduced price caps for DiGAs once they reach 2,000 prescriptions — a form of volume-based pricing — even if they remain in the provisional phase, and they also apply when they enter their second year of permanent listing. In 2024, these therapy area maximums range from €518 to €681 based on the positive care effect demonstrated by other DiGAs in the same category (€585 average).[239] Additionally, DiGAs in the lowest pricing quartile were made exempt from price negotiations if their annual sales remain below €750,000.[239]

Following the provisional phase, DiGAs that demonstrate value and qualify for permanent listing must negotiate final prices with GKV-SV, which often result in significant price reductions.[240] For example, Elevida, a neurological disorder app, saw its price reduced by 67%, while Velibra faced a 52% cut.[241] An analysis of provisional-to-permanent DiGAs price differences found that negotiated prices were, on average, 29% lower than initial manufacturer prices by September 2023 and 47% lower by July 2024 — with some therapy areas seeing reductions of 50% or more. By July 2024, most permanently listed DiGAs were also reimbursed in the €200–€300 range, with an average price of €226 (Exhibit 34).[239] Although most negotiations lead to lower prices, at least one tinnitus app secured a higher permanent price, and three retained their original pricing. As manufacturers are also now required to repay the difference between provisional and final prices after the first year, this drop adds a layer of financial risk for developers.[239]

Germany has made other efforts to ensure that DiGA deliver their promised value including performance-based pricing. For instance, DigiG and DiGAV-AmendV-E laws introduced partial value-based reimbursement for at least 20% of DiGA payments through a mechanism called AbEM (Anwendungsbegleitende Erfolgsmessung).[242] This approach ties reimbursement to usage metrics — such as frequency, duration, and completion rates — as well as patient-reported outcomes measuring satisfaction and health impact. While intended to reward real-world effectiveness, manufacturers have criticized the model as a form of "double devaluation," arguing that discontinuation rates already influence negotiated pricing, and expressed concerns that it would increase the cost of data collection, potentially requiring the licensing of validated instruments for PROM collection. They also questioned the need for rigid expectations duration or frequency of use, as long as therapy was successful with patients experiencing the intended positive care effects.[243]

Other policy changes have sought to improve and expand app use within care, but these expanded opportunities have come without provisional

Exhibit 34: Price per prescription for DiGAs by therapy area, provisional vs. permanent listing (July 2024, €)



Source: DiGA Directory from the Federal Institute for Drugs and Medical Devices (BfArM), Available from: https://diga.bfarm.de/de/verzeichnis
Notes: Most prescriptions are 90-day, but some are one-time license. Sleep included in mental health and excluded from nervous system. Chronic pain category overlaps muskuloskeletal pain.

reimbursement and therefore require confirmatory evidence prior to approval. For instance, the DiPA reimbursement pathway for use of home-care and nursing applications in long term care was launched in October 2022 offering €50 per month for app use (€53 with supplementary support services), but still hasn't approved its first reimbursable app.[244,245] Unlike DiGA, where reimbursement is tied to a prescription, DiPA apps are listed in a central directory, and whether to reimburse is determined by the long-term care insurance fund.

Finally, it has also taken steps to facilitate digital care. While physician follow-up for DiGA use has been reimbursed at just €7.93, proposals have been made to allow billing for education and therapy support, enabling blended care models that combine digital and in-person services.[239,246]

Finding the right balance in Korea

Finally, finding the right balance of incentives within a national system to support emerging innovation while managing long-term costs can be challenging. In Korea, the Ministry of Health and Welfare (MOHW) introduced IRAS in late 2022 to allow innovative medical devices to benefit from accelerated approval and temporary reimbursement for three years while collecting evidence for full evaluation — similar to Germany's DiGA and France's PECAN.

The goal of the integrated approval/reimbursement process under IRAS was to shorten the timeline from approval to coverage from 390 to 80 days while establishing a value-based compensation system for them. In practice, only two of the first four IRAS-approved DTx decided to pursue temporary reimbursement and were granted it ~8–10 months post-approval. This was reported to be largely due to the requirements for developers to submit pilot study plans to NECA across multiple hospitals, integrate their solutions into hospital EMRs, and train patients and providers.[136]

However, temporary reimbursement rates in Korea may also have been a factor. The three-part reimbursement structure for IRAS-approved prescription DTx, introduced in August 2023 included a:[247]

- **Prescription fee**: ₩5,230 (~USD $4), paid to the prescriber for issuing the digital therapeutic and providing initial education and guidance on use (app installation) precautions, etc.
- **Evaluation fee**: ₩16,130 (~USD $12), paid to providers to evaluate outcomes and the effectiveness of the DTx device after therapy completion, including usability and treatment effects such as symptom improvement or reduced medication intake — and retroactively for managing the ongoing treatment plan.
- **Base DTx use fee**: ₩10,000 (~USD $8), subject to a 90% patient co-pay under Korea's selective benefit system. This fee can be revised upwards based on a cost calculation table detailing various components — Including development costs, operational costs, comparative pricing of similar therapies and submitted cost-effectiveness analyses — and a final approved use fee is set by Health Insurance Review and Assessment Service (HIRA) with payment that can later be adjusted based on real-world usage and feedback.

Unlike in Germany where provisional rates were set at a rate intended to support long-term product development and clinical validation (but also led to concern that taxpayers were bearing the cost of unproven solutions) those in Korea are set low during the IRAS' three-year evidence generation period. Companies can choose for their products to be "non-reimbursed" or to obtain temporary reimbursement (selective benefit), but even at reimbursed rates, patients bear 90% of the cost during the trial period (the insurer covers just 10%). This approach intentionally keeps public spending low until its clinical effectiveness is proven, although this approach facilitates usage tracking. However, these rates were criticized as not reimbursing doctors for the actual workload for integrating DTx into practice and raised concerns about whether DTx developers can sustain operations and invest in further research during those three years.[133,248]

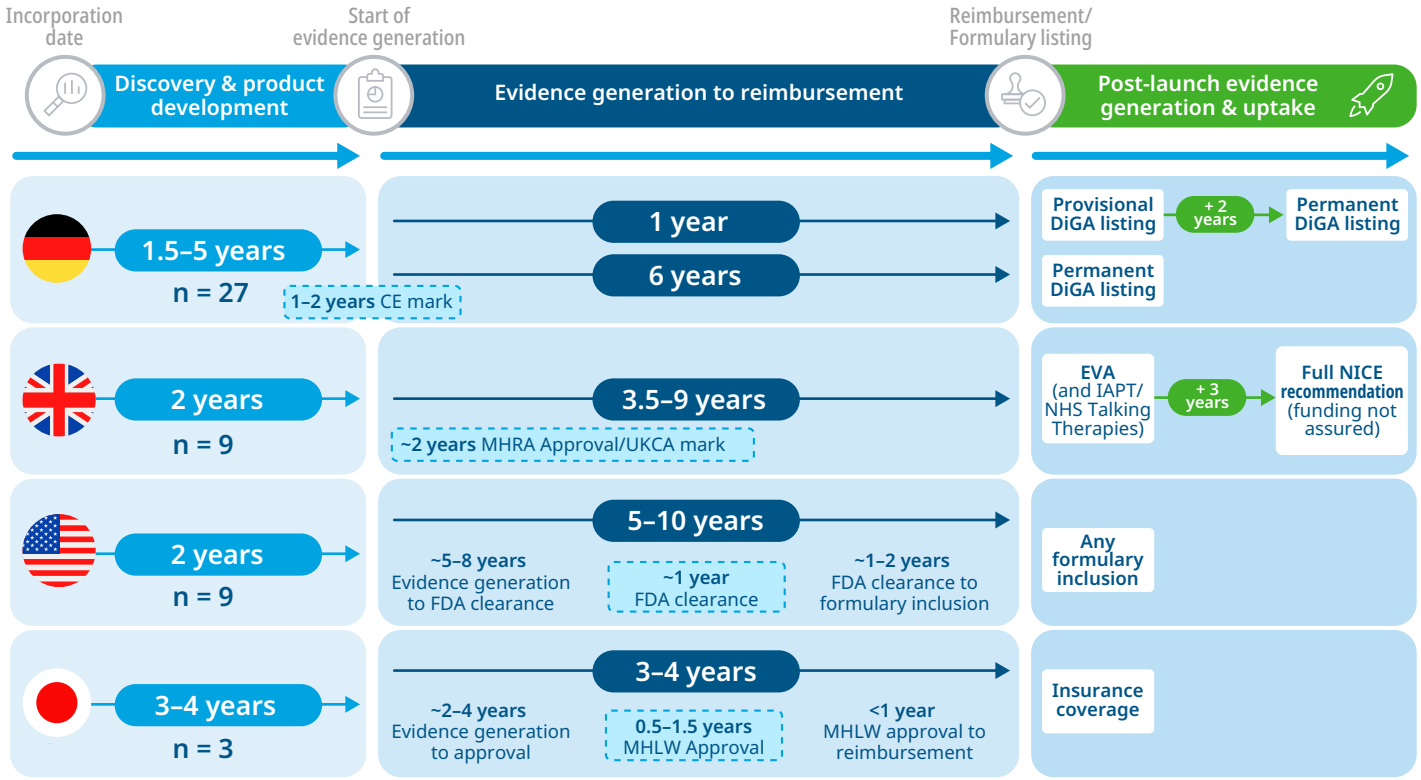
Based on the low use fees, some developers opted not to enter the reimbursed system. For instance, when Somzz, for insomnia, was assigned a reference price of around ₩25,390 (~$19) — reportedly calculated based on its incurred product development costs — its developer, AimMed, decided instead to offer its product at a "non-reimbursed" rate of ~₩250,000 (~$190) for one treatment cycle of six weeks, which is below the patient out-of-pocket costs for six weeks of reimbursed cognitive behavioral therapy.[249,283] The low temporary reimbursement rates, which have been 10x–20x below the non-reimbursed price, raised concerns that public reimbursement was unlikely to support continued product development costs or that of a full clinical development program, and that even after full approval reimbursement might be low.[250] Some also lamented uptake lagging in Korea compared to other countries, where by mid-2025, only around 200 digital therapeutics prescriptions had been written compared to ~2,000 in Japan.[248]

TIME TO REVENUE

To assess the growing viability of the digital health marketplace, it is useful to examine how quickly developers are securing revenue or reimbursement across geographies, and whether this pace is accelerating. An analysis of development timelines for digital therapeutics (DTx) and key milestones like the start of product development, evidence generation, regulatory approval and reimbursement reveal notable differences across markets and a clear evolution over time.

Specifically, a study of DTx for mental health and neurological conditions conducted at the end of 2023 found the time from company incorporation to revenue opportunities ranged from as little as 2.5 years to gain provisional reimbursement in Germany, to 5.5–7 years in other markets (Exhibit 35 and Methodology). Product development timelines ranged between 1.5–5 years across markets with some regional variation and regulatory approval timelines were more consistent

Exhibit 35: Approximate time to revenue for digital therapeutics in the CNS and mental health space (as of Dec 2023)



Source: IQVIA, Analysis conducted Dec 2023.

Notes: In the UK, NICE EVA recommendation does not mandate use nor funding by NHS. In the United States formulary inclusion is gained payer-by-payer. Japan approvals include DTx outside of the CNS space. Japan reimbursement time analysis included two DTx outside of the CNS space. EUDAMED database contains CE marking information for subset of solutions (e.g. HelloBetter) however CE marking dates are not routinely accessible.

across markets, with FDA clearance taking approximately one year in the United States, CE marking taking 1.5 to two years in Europe, and MHLW approval taking between 0.5 and 1.5 years in Japan. In the UK, self-certification for UKCA Class I devices can be completed relatively quickly though for Class IIa products to obtain a CE or UKCA mark, an ISO13485-compliant Quality Management System must be implemented and certified, which typically takes around nine months.

The next phase — evidence generation, defined as the period from the start of the first pivotal or DiGA-referenced trial to any formalized coverage — shows significant variation across markets due to differences in pathway maturity and national approaches to digital health solutions. In Germany, the most advanced market for digital solution reimbursement, this phase can be as short as one year before provisional coverage is granted.

In contrast, the United Kingdom and United States, where robust evidence can be required for formulary inclusion and reimbursement decisions are more fragmented across different payers and decisionmakers, timelines are longer. In the UK, most products assessed by Early Value Assessment (EVA) in 2023 had 3.5–9 years of evidence and the solution to receive full NICE recommendation, Sleepio, had nearly 10 years of evidence. Products following the EVA pathway require an additional three years of evidence generation prior to NICE re-assessment for full reimbursement.

In Japan — where the analysis included approvals in any therapy area — evidence generation timelines were generally shorter for the three products assessed by the Ministry of Health, Labour and Welfare (MHLW) and took 3–4 years, with minimal delay between regulatory approval and reimbursement.

Since 2023 there has also been some indication that the time it takes for developers to gain reimbursement (time-to-revenue) is diminishing over time. As the DIGA pathway and other national pathways evolve and developers more skillfully leverage their pre-existing and pre-validated platform infrastructure and tailor it to specific conditions, become better at addressing the needs of health stakeholders, digital therapeutics to obtain temporary reimbursement within 2–3 years.

Apart from regional variation, development and commercialization timelines of digital solutions have also shifted over time. While "first generation" DiGA-listed solutions, such as Deprexis, gained reimbursement after 7–10 years, manufacturers of "second generation" digital therapeutics have been able to capitalize on learnings from early launches — sometimes of their own first product and sometimes a competitor's — and thus took less than three years on average to gain permanent reimbursement.

First generation products notably required initial development of platform software and developers gathered substantial evidence prior to submission over a long period of time (up to six years) allowing them to directly file for permanent listing. And these developers also gained critical insights during evidence generation and regulatory approval and undertook significant market-shaping efforts. In contrast, second-generation or "follow-on" solutions have leveraged provisional listing more strategically to streamline timelines, allowing evidence generation to continue post-launch., enabling earlier revenue generation. These products typically maintained their provisional status (already reimbursed) for about two years while building necessary evidence. Indeed, most currently provisionally listed CNS DiGAs began their required comparative trials only after receiving provisional status, extending the provisional listing period to 1.5–2 years in practice, drawing criticism from the GKV-SV in its 2023 report. DiGA guidelines state that provisional listing should exceed one year only in "exceptional cases," and expressed concern that with this extended duration becoming more common, the weaker supporting evidence may hinder provider adoption.

Multi-condition regulatory approval for Software as a Medical Device (SaMD) platforms may also help accelerate time-to-reimbursement for some digital solutions. Platforms such as Huma, which operate across multiple markets with unified cybersecurity and data privacy policies, illustrate the potential for broader regulatory recognition. Additionally, emerging frameworks — such as those for managing expected modifications to AI-based software, predetermined change control plans (PCCPs), and off-the-shelf (OTS) software used in medical devices — are expected to further accelerate time-to-reimbursement by reducing regulatory validation.[251,252] These approaches may also streamline development of infrastructure that can be expanded to host multiple solutions and simplify subsequent regulatory filings, ultimately speeding access to reimbursement for future disease management solutions.

Evidence trends and payer requirements

+ **Evidence generated on digital health solutions has rebounded from a post-pandemic dip, driven by growth in efficacy studies that demonstrate their value, but health economic studies lag despite growing importance to payers seeking evidence of cost effectiveness.**
+ **Meta-analyses and systematic reviews now account for 21% of efficacy studies in 2024, signaling a maturing evidence base for digital health solutions and reflecting a global consolidation of thinking on their role in care.**
+ **Payer requirements for reimbursement vary across geographies but are gradually converging, with most frameworks now expecting developers to demonstrate clinical benefit through one or more randomized controlled trials, conduct studies that include the local population, and compare their solutions against the standard of care.**
+ **Evidence generation plans now ask developers to demonstrate impact on resource use and provider workload, success and system-level impact in intended care settings, and clearer proof of benefit in the target population — reflecting rising expectations for cost-effectiveness and real-world applicability.**
+ **Formal and informal requirements in most geographies for locally run studies have heightened the need for a global evidence strategy, enabling developers to manage complexity and mitigate costs.**
+ **Beyond formal clinical and economic requirements, payers and care organizations often add criteria to ensure operational fit with existing benefit structures and care pathways, and confirm partner readiness in terms of financial stability, experience, technical capabilities for integration and data reporting, and ability to scale.**

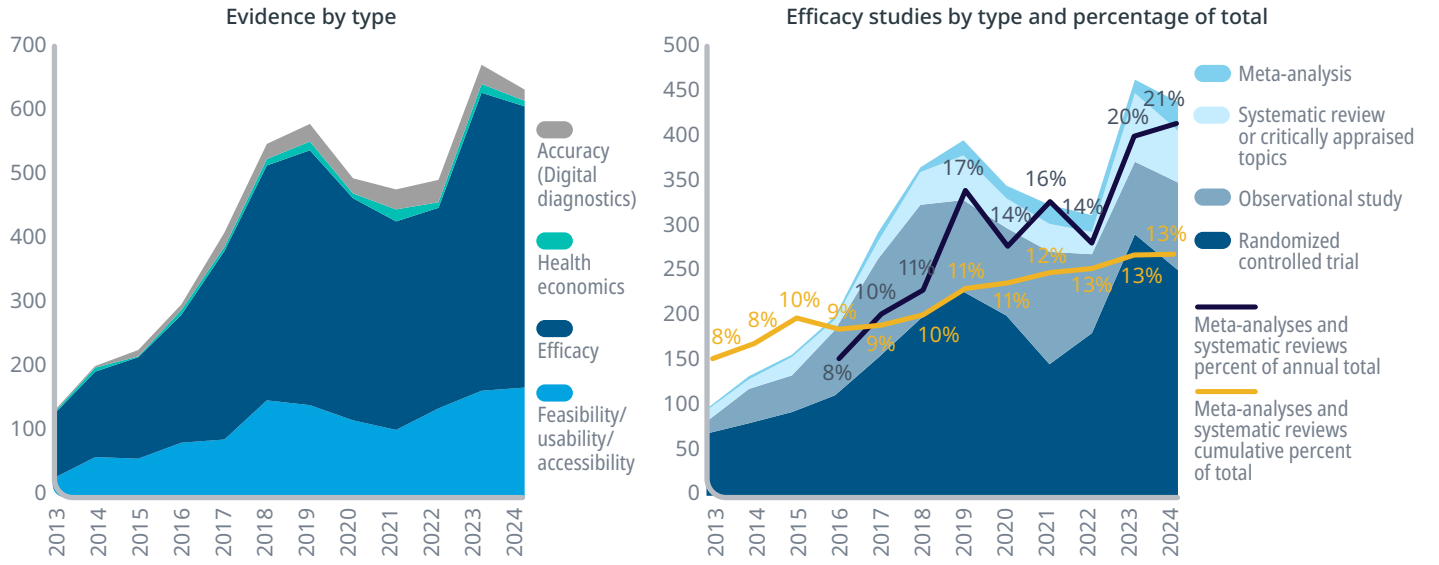
TRENDS IN EVIDENCE DEVELOPMENT

The need for digital health solutions to generate robust evidence continues to grow as payers have codified their criteria for digital health technology assessment and demanded higher quality evidence. Renewed interest by providers and other stakeholders to explore the value of digital tools within care settings — combined with the rise of temporary reimbursement pathways focused on evidence generation — has also accelerated the opportunities that digital health solutions have to prove their value in real world settings.

As a likely result, the number of published efficacy studies has rebounded since a post-pandemic dip and included studies conducted in at least 42 countries in 2024. Although understanding the cost effectiveness of digital health solutions is becoming increasingly important to payers, health economic studies still lag, however (Exhibit 36). Among efficacy studies, meta-analyses and systematic reviews now account for one-fifth of all evidence — 21% of studies in 2024 — signaling that the evidence base for digital health solutions is growing and maturing. Similar to national health technology assessments, these analyses reflect a consolidation of thinking about the role of digital technologies in care globally.

Evidence continues to grow supporting the use of digital tools to address patient mental and behavioral health needs, along with applications neurology, oncology, obstetrics and gynecology and pediatrics (Exhibit 37). Additionally, within those areas, digital tools have broadened in their applications and span multiple uses within each category.

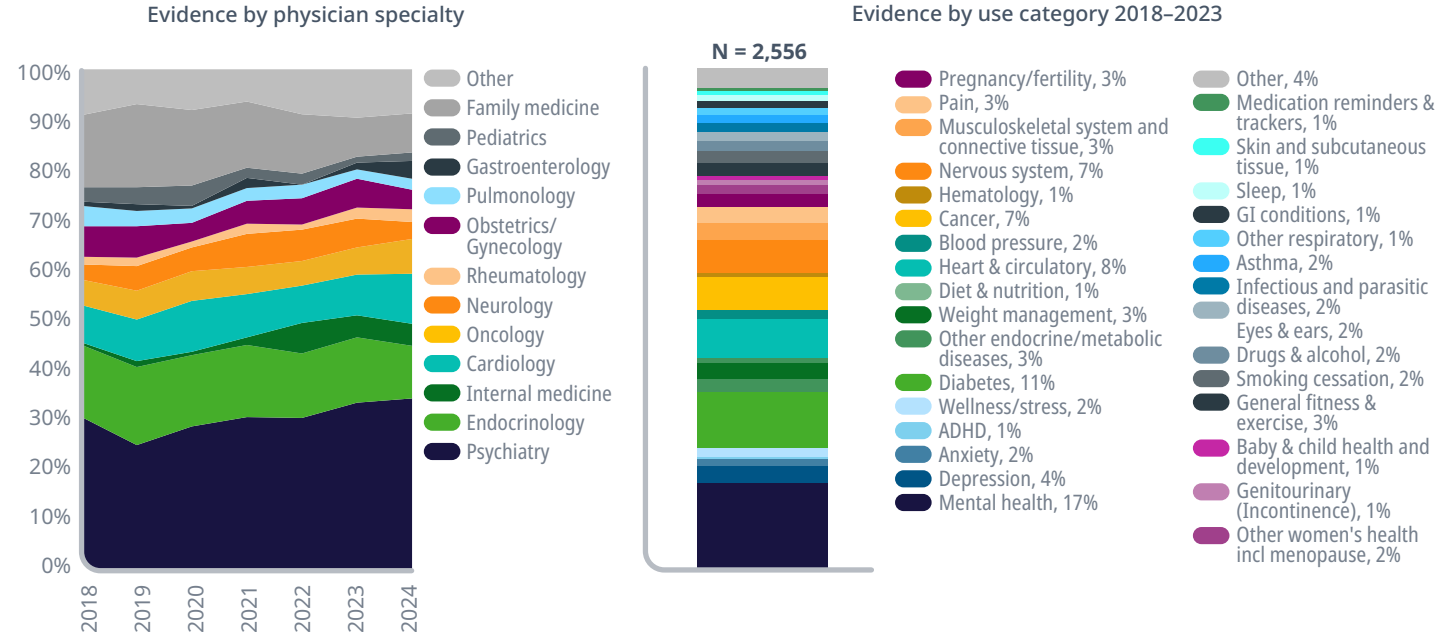
Exhibit 36: Published digital health studies by type and level of evidence



Source: IQVIA Institute, May 2025; IQVIA AppScript Clinical Evidence Database, May 2025.

Notes: Efficacy studies only include those evaluating the interventional value of a digital health solution (mobile or web app, connected device, or other mobile intervention such as texting) on patient outcomes such as activity levels, lab results, or healthcare resource utilization.

Exhibit 37: Evidence generation by therapy area and percentage of total published evidence



Source: IQVIA Institute, Jun 2024. IQVIA AppScript Clinical Evidence Database, April 1, 2024.

Notes: Displays pieces of published evidence. For left chart, displays percentage of 543 evidence pieces in 2018 and 540 in 2023.

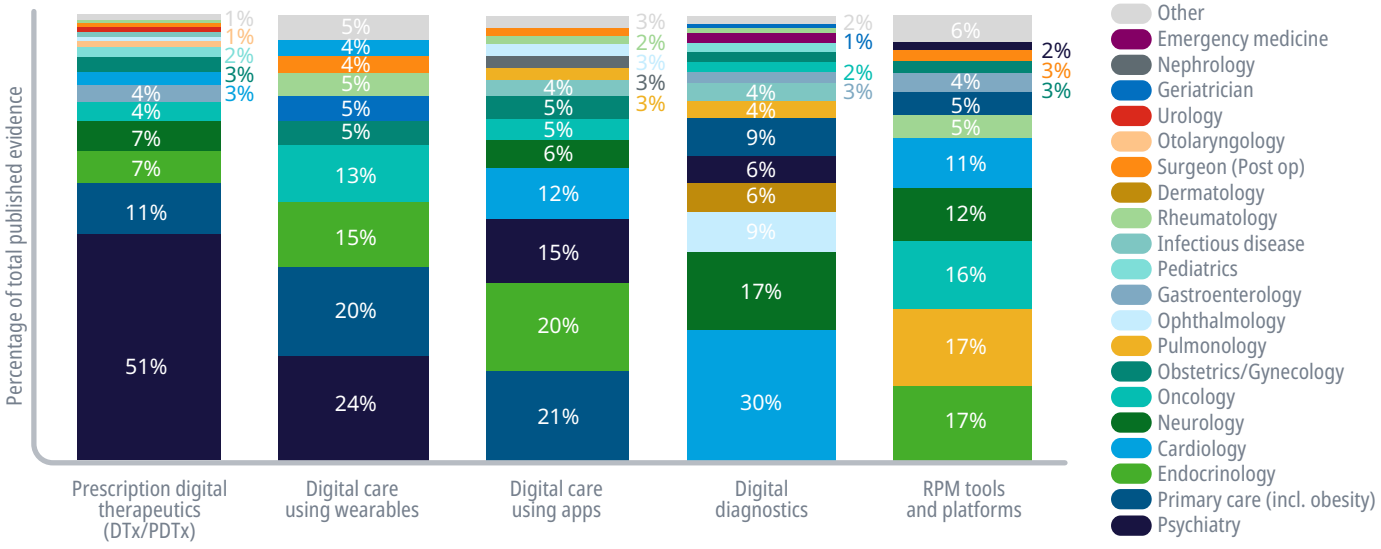
"In a significant shift… independent committees can assess every technology based on their overall cost-effectiveness and benefits to patients and services. These changes aim to accelerate the adoption of effective devices, digital and AI solutions and diagnostic tools that can transform patient care and outcomes across the NHS." [113]

— NICE, regarding its HealthTech programme.

As digital health tools have expanded and diversified in recent years, they have evolved into more clearly defined categories of innovation, each serving distinct clinical audiences and areas of application (Exhibit 38). For each solution type, evidence has emerged supporting differentiated use cases:

- **Digital therapeutics** have demonstrated effectiveness in supporting behavior change and mental health interventions, particularly for patients with psychiatric conditions (e.g., depression, anxiety, insomnia) and in metabolic disorders such as diabetes, obesity, and weight management, as well as other chronic conditions commonly managed in primary care.
- **Digital care programs** incorporating exercise regimens and behavioral interventions have shown success in improving outcomes for cancer patients, cardiac rehabilitation (including hypertension), and older adults by providing holistic support. They are increasingly used to extend care beyond traditional settings, including pregnancy support and geriatric care.

Exhibit 38: Medical areas of application for digital products, based on published evidence



Source: IQVIA AppScript Clinical Evidence Database, May 2024.

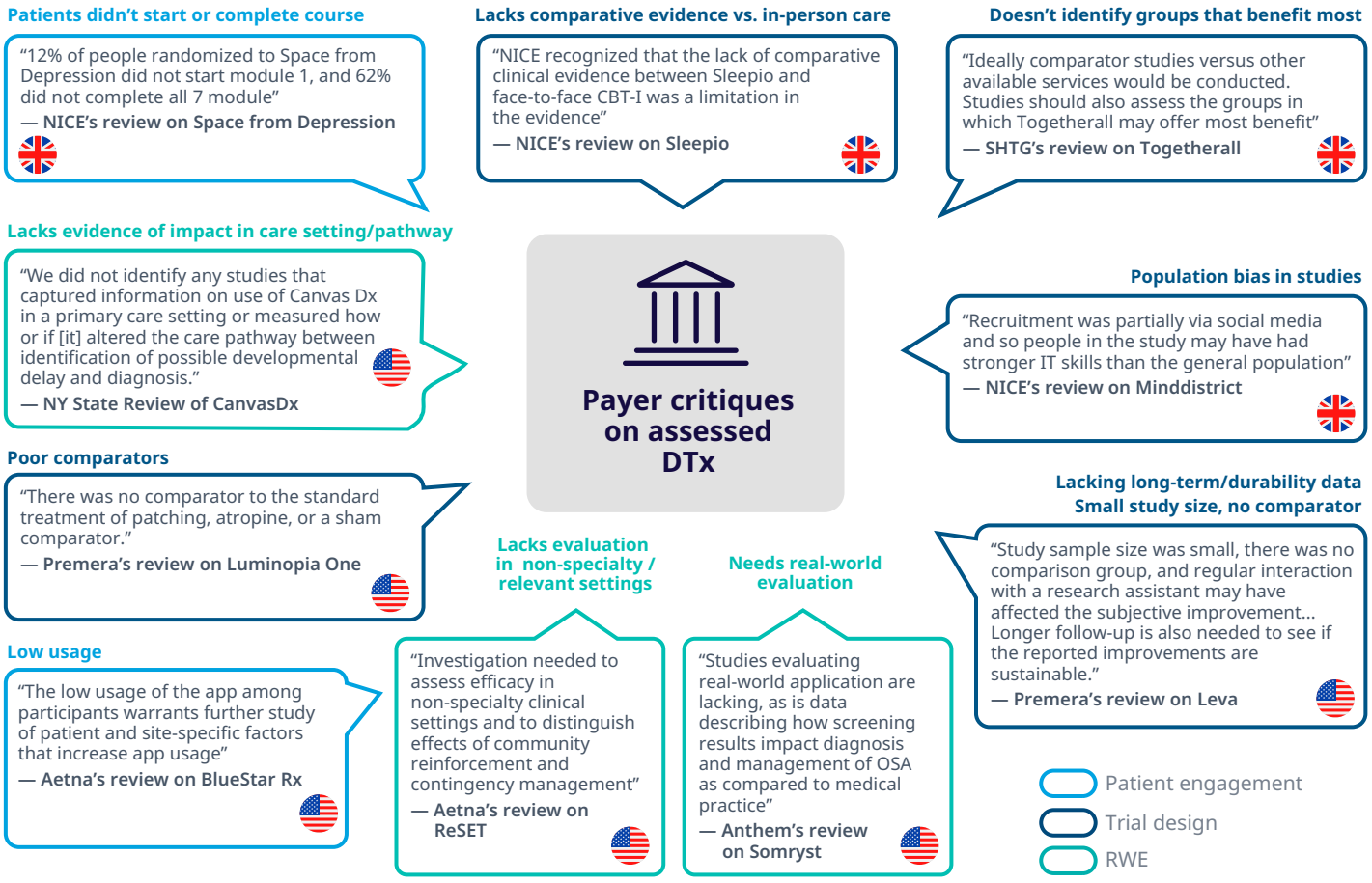
Notes: Digital care includes all coached interventions. Bottom 10% in each category assigned to other for visualization purposes.

- **Digital diagnostics and sensor-based technologies** enable remote and point-of-care assessments across a range of specialties, including cardiology (ECG, heart failure algorithms), ophthalmology (vision screening, diabetic retinopathy AI tools), dermatology (skin lesion analysis), psychiatry, and neurology (cognitive and behavioral assessments). Emerging evidence also supports their use in pulmonology and infectious disease.
- **Remote monitoring technologies** have built evidence of their effect managing conditions such as asthma and COPD (smart respiratory sensors), diabetes (continuous glucose monitors), oncology (electronic patient-reported outcome apps), neurology (EEG-based tools), and cardiology (ECG-enabled devices, heart failure monitoring).

GLOBAL EVIDENCE REQUIREMENTS FOR DIGITAL THERAPEUTICS

As evidence supporting the use of digital solutions continues to expand and evolve, payers have gained clarity on what they view as best practices in clinical evidence generation and have begun to codify these into published standards. This evolution of assessment criteria was driven in part by payer dissatisfaction with the clinical evidence submitted to them by digital products that entered the market early — which often lacked rigorous comparator design, were not used in the care settings they were intended for, relied on surrogate endpoints, or only demonstrate real-world impact in narrow populations or over a short period of time (Exhibit 39).

Slide 39: Payer critiques of clinical evidence for digital therapeutics



Source: IQVIA Institute Jul 2024. IQVIA research into publicly available evidence packages submitted to payers in markets and relevant reviews.
Notes: May not be indicative of overall evidence published for a particular solution. Scottish Health Technologies Group (SHTG).

As a result, global payer evidence requirements and expectations are beginning to align across key markets (Exhibit 40). Payers now increasingly expect developers to demonstrate benefit through randomized trials, conduct clinical studies that include the local population, and compare their solutions against standard of care to demonstrate benefit to access most national reimbursement pathways. Some also require evidence of cost-effectiveness before considering reimbursement. These expectations have gradually been codified in national-level evidence criteria, which for digital therapeutics can be classified into three categories:

- **'formal'** requirements describing mandatory evidence needs, captured within official payer guidance
- **'non-mandatory'** recommendations captured within official payer guidance as not mandatory, and
- **'informal'** evidence and standards not captured within official guidance but known to be considered by payers based on their review of other digital therapeutics or identified through market research

However, some important differences in requirements remain among countries, and evidence requirements may further vary based on the nature and objective of each solution. Even within a country, there can also be wide variation. For instance, in the United States where multiple large commercial payers like Aetna, Anthem and Premera have been grouped together, each payer may have different standards. And in countries with early innovation pathways that often grant temporary reimbursement like France (PECAN), Germany (DiGA) and the United Kingdom (EVA) and others, requirements often differ from permanent pathways — often allowing fast-track entry based on demonstrated potential benefits, meeting safety standards, and obtaining a CE mark.

Randomized controlled trials

Taking a more in depth look at these requirements shows that payers increasingly expect developers to demonstrate clinical benefit through one or more randomized controlled trials (RCTs) with an appropriate comparator equivalent to the standard of care. This expectation directly impacts development timelines and the up-front investment required for health tech manufacturers. Although only U.S. commercial payers and France's medical device authority (CNEDiMTS) explicitly mandate RCT data for permanent reimbursement, a randomized controlled trial is strongly preferred even when not formally required. This preference has made randomized controlled trials a de facto requirement for most payers and will likely become mandatory in key markets such as the United Kingdom, Germany, and Japan. For example, NICE clearly states its preference for randomized controlled trials (though high-quality comparative real-world evidence studies may be acceptable), and while DiGA does not formally require RCTs, all early DiGAs in mental health that achieved permanent listing submitted data from at least one randomized controlled trial. In France, the new PECAN fast-track pathway may grant temporary reimbursement before an RCT is completed, but only if an adequate trial is already well underway.

Additionally, as whitespace is gradually filled and a leading digital health solution comes to the fore, the need to produce high quality evidence with greater numbers of patients will likely increase. For instance, the fact that Sleepio presented 12 RCTs upon its submission, is likely to raise the bar for future submissions in the insomnia space. As mature use cases for digital therapeutics have emerged, the most mature applications also notably have the greatest number of enrolled patients per randomized controlled trial (Exhibit 41).

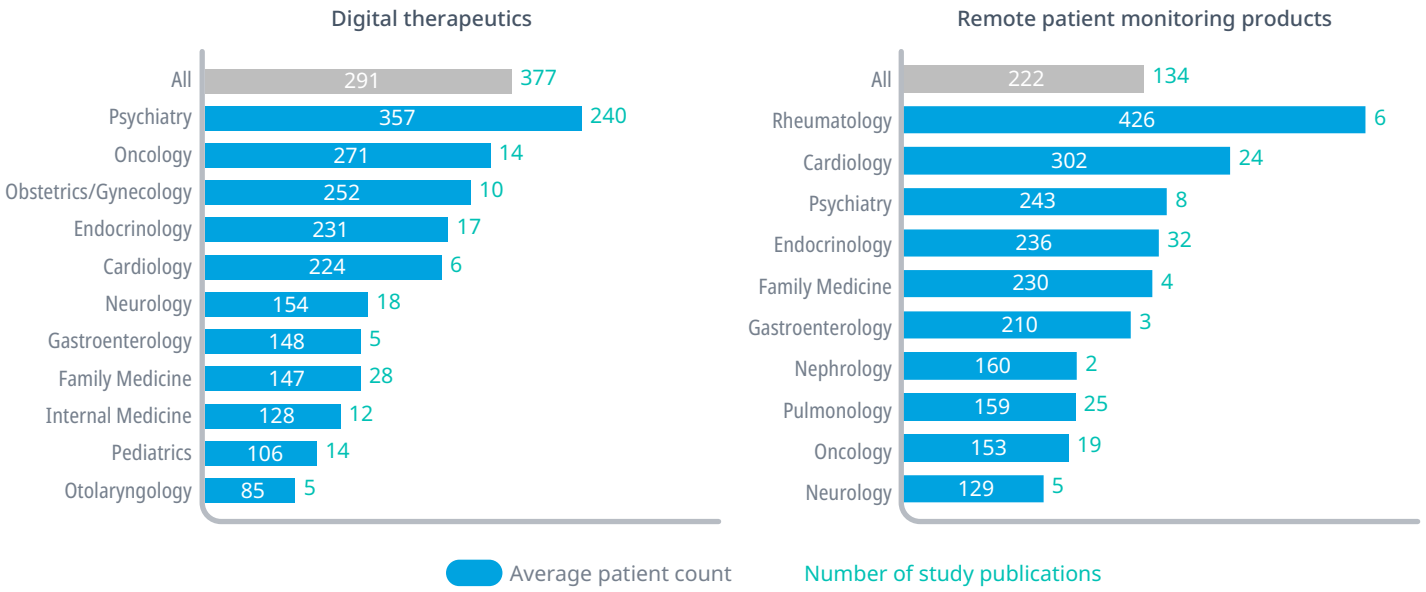
Exhibit 40: Evidence requirements across mature markets

Evidence Requirement	U.S. (MCOs)	UK		DE		FR		JP	
		Temporary	Permanent	Temporary	Permanent	Temporary	Permanent	Temporary	Permanent
Medical benefit through an RCT		"Plausible potential"						Exploratory clinical or RWE	Confirmatory post-market or RWE
Study with a local population	US population mandatory; payer population informal	Setting relevant to UK population		Not mandatory but approval based on transferable population data is rare				Exceptions for rare diseases	
Comparison vs. standard of care									
Well-defined population									
Medical benefit in a real world setting				RWE accepted				Not mandatory, can be requested	
Safety		Required for AI-SaMD	DTAC compliance	CE Mark		CE Mark		Quality assurance, safety management system requirements	
Health economics		Cost-utility or cost-comparison, impact size & likelihood	NHS care efficiencies, cost effectiveness	GKV price negotiations once the DTx is permanently listed includes health economic components		Not assessed by CNEDiMTS			
Multiple clinical studies (any type)				Many DiGA approved with one RCT					
Patient-relevant outcomes	Not specified in payer policies				To influence 20% of price	Quality of life and accepted scales			
Patient engagement (use)	Required by some payers				Required post market				
Durability of medical benefit (effect)		Depending on indication				Long-term quality of life data essential		Annual post market surveillance data sometimes	

Formal requirement / required by some payers	Preferred but not mandatory	Informal benchmark	Informal now but likely future requirement	Not required	N/A

Source: IQVIA; Aug 2025.

Exhibit 41: Average enrollment in randomized controlled trials for digital solutions by type and specialty



Source: IQVIA AppScript Clinical Evidence Database, May 2024.

Notes: Includes published randomized controlled trials (RCTs) since 2004. Left chart excludes digital therapies assumed to be NDTs. Right chart includes digital tools and platforms for remote patient monitoring.

At the same time countries may also accept real world evidence from reliable and high-quality data from real-world medical environments to support approval and reimbursement of digital solutions. For instance, Korea's Ministry of Food and Drug Safety (MFDS) in 2023, began recognizing Real-World Evidence (RWE) as clinical trial data to demonstrate safety and efficacy when approving digital technology-based medical devices.[253]

Studies including the local population

Including the local population in randomized trials is a critical requirement in most markets — both formally and informally — and directly influences the cost of developing a global reimbursement strategy. In the United Kingdom, local pilot studies are often sufficient for Integrated Care Boards (ICBs) to authorize regional reimbursement. However, full approval from NICE may ultimately require randomized controlled trials (RCTs) or comparative real-world studies that include UK patients. In the United States, certain health systems, such as the VA, similarly require local pilots in their covered populations alongside national RCTs. In Germany, while studies involving the local population are not explicitly mandated if the study population is deemed comparable to the German population, in practice, very few DiGA have received permanent listing based solely on non-German data.

Comparison versus standard of care

To demonstrate the efficacy and value of digital solutions, payers across markets are increasingly mandating that solutions be compared to the current standard of care. However, the level of guidance provided by payers vary, and definitions of "standard of care" often reflect the current reality of care within a specific indication and healthcare setting.

For instance, in some markets, comparing mental health digital therapies to passive controls — such as waitlists — may be appropriate, especially where provider shortages limit system capacity and access to care. In other cases where the standard of care is face-to-face therapy, trials may be run where both groups receive in-person care, but only one uses a digital solution or receives blended care. For instance, a 2023 IQVIA review

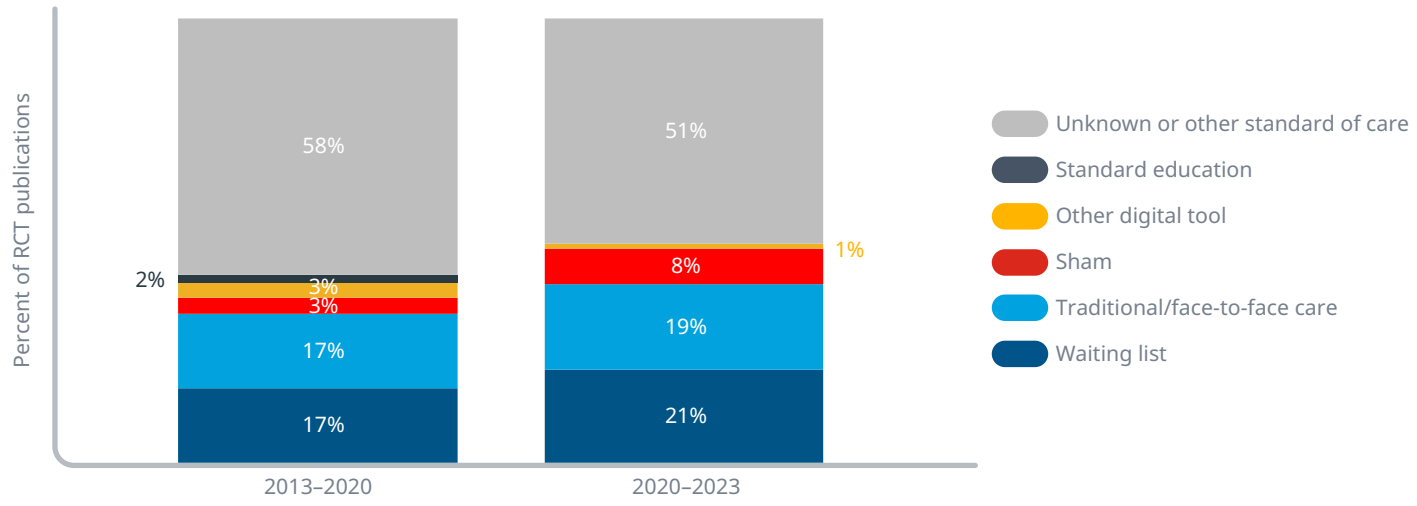
of 43 studies submitted by developers in the mental health space (n=16) to gain reimbursement for 16 digital therapeutics found that 70% used waitlist controls (N=30), 16% used other online therapies, and 14% used face-to-face care.

However, even if it reflects the reality of care, increasingly, payers are requesting comparisons to active interventions with known therapeutic effects, such as existing digital solutions or face-to-face cognitive behavioral therapy (CBT), rather than to waitlists. This makes it likely that digital solutions will eventually need to go head-to-head against currently marketed digital health solutions. For example, NICE requested Sleepio be compared to face-to-face CBT-I, and in the U.S., Freespira — a biofeedback-based digital therapeutics for panic disorder and PTSD — was tested against a mindfulness app recommended by the U.S. Department of Defense.[254] While not yet standard, this approach is gaining traction and may lead to more head-to-head comparisons with leading digital health solutions.

The FDA has also requested control arms that use "sham" digital health apps that mimic therapeutic design but lack active components in some randomized trials, including those involving VR-based therapeutics.[255] The use of sham comparators increased through 2023, even as the use of active comparators have decreased as perhaps indicating it may be a preferred route for developers (Exhibit 42). However, it may also indicate that solutions are being created increasingly in areas of unmet need and not just replacing prior digital technologies.

This is because sham comparators are especially useful where no similar solution exists. As an example, MedRhythms' InTandem — a digital therapeutic that increases a patient's gait by having them walk to a musical beat modulated by shoe-located sensors — needed to create a sham therapy comparator. To do so, they removed the therapeutic component (music modulation) and had the control arm perform the therapy without music, thereby controlling for the possible benefit of walking and physical exercise.[256] Similarly, AppliedVR used a sham VR experience for a chronic pain digital therapeutic where the control arm removed the visual guided imagery and delivered VR with neutral non-interactive content.[257]

Exhibit 42: Comparators used in randomized controlled trials for digital therapeutics



Source: IQVIA AppScript Clinical Evidence Database, May 2024.

Notes: Excludes products assumed to be non-prescription DTx (NDTs). Waiting list includes no care and delayed care. Sham includes all like-to-like comparisons and attenuated devices (e.g. App-to-app, device-to-device, sham). Other digital tool includes comparisons of digital care using DTx to DTx alone, DTx to evidence-based NDTs, etc. Standard education includes paper or other standard methods.

However, controlling for possible benefit from the for digital experience or user experience sham app and VR experiences can pose its own challenges, and there have been cases when sham apps themselves were too good and proved to have positive effect themselves.[258]

Other emerging requirements

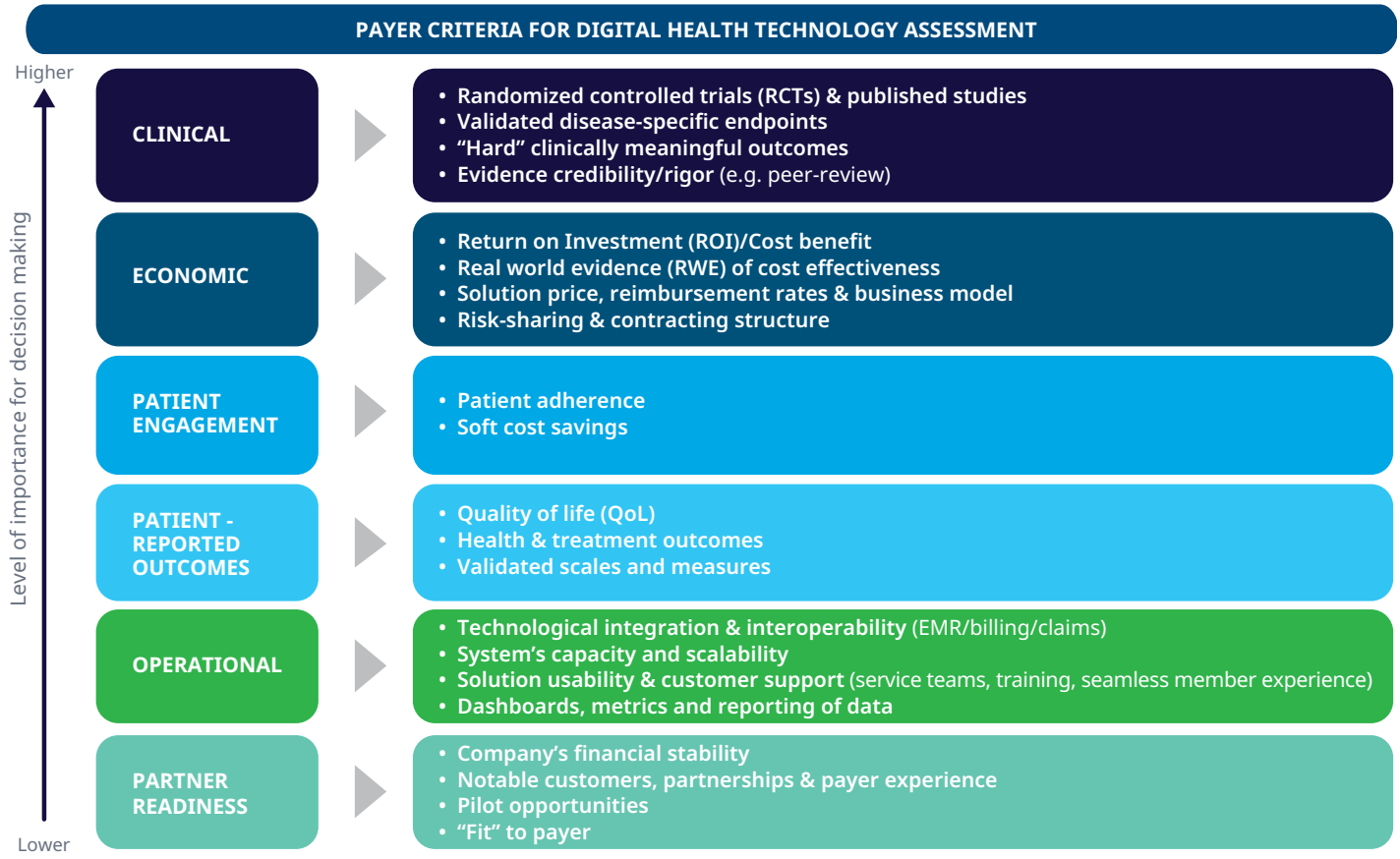
Those making purchasing decisions emphasize robust clinical and economic evidence as reimbursement criteria, but payers have indicated other criteria are also a factor (Exhibit 43).

Ongoing collection of patient engagement metrics

While not yet a formal requirement across markets to gain initial reimbursement, patient engagement metrics are gaining importance as a requirement to maintain reimbursement once solutions reach the market and are evolving beyond adherence. Payers have criticized digital solutions for having high attrition rates in submitted trials and have gradually built strategies to modify payments for this imperfect delivery of value.

Requirements have been added to include data on durability that may guide the reimbursement prices set, and reimbursement amounts may be modified initially or through ongoing monitoring. For instance, countries with early access pathways are implementing data collection requirements as part of evidence generation to help guide later decision-making, such as with the DiGA pathway. In the U.S., some payers now also make continued reimbursement contingent on a specific patient's level of engagement.[155,156] In France, CNEDiMTS

Exhibit 43: Criteria for digital health technologies to gain reimbursement in the U.S.



Source: IQVIA Payer Interviews; 2023; IQVIA Expertise.

> *"The other thing that insurers, payers, and providers are worried about is the durability of the effect. Patients use them for 3 to 6 months, and then they're done. Payers are [thinking], "You've shown me 6 months of data. That's terrific. It looks like it's effective, but I want to know what the effects are at 12 months or 2 years. Do I have to pay for re-treatment?"* [260]
>
> *— John Fox MD*

requested that Deprexis provide real-world data on duration of use, frequency of use, number of logins, and time to first use in the French population and NICE has requested data from vendors on attrition, adherence and the reasons patients stop treatment.[259]

Evidence gaps

As many national pathways have been created in part to facilitate high-quality evidence generation among digital solutions to support their integration into established care models, the evidence gaps they identify in their early assessments highlight what payers view as continued barriers to adoption. For instance, as NICE works to figure out the right place for various digital solutions within national care has focused feedback within its EVA guidance on the need for solutions to build evidence supporting their place in specific care settings (e.g., primary care, surgery, aging clinics, home use), and in specific patient populations (e.g., surgical or high-risk patients) and cost savings in the context of provider time and resources.

Payers are increasingly seeking comprehensive health economic data to understand cost-effectiveness and model budget impact. In the United Kingdom, NICE aims to confirm not only that any digital solution permitted for use is cost-effective, but also that the assumptions underlying its cost-effectiveness assessment will be realized in practice. For example, across its Early Value Assessments (EVAs), NICE requested evidence to ensure benefits would materialize, including:

- **Resource utilization** — Impact on provider time and visits during and after treatment, including the level of care provider involved (professional grade and time/visits). In Germany, while required DiGA endpoints exclude staff workload and health economic impacts, such evidence is critical for price negotiations with GKV-SV.
- **Setting-specific success** — Proof of effectiveness in the intended care setting (e.g., UK primary care, surgery, aging clinics, home-based use), since original studies may involve different populations or provider types. In the UK, technologies are expected to integrate with existing NHS systems.
- **Sub-population outcomes** — Evidence of success in the target population (e.g., surgical patients or high-risk segments). Payers also assess appropriateness for underserved populations and their user experience, creating opportunities for apps that improve healthcare accessibility.
- **Contextual data** — Baseline demographics, risk classification, symptom severity, and impairment levels.
- **Tiered benefit levels** — Rates of patient recovery, reliable recovery, and reliable improvement.
- **Engagement metrics** — Attrition, adherence, completion rates, and reasons for discontinuation.
- **Failures** — Rates of relapse, adverse effects, or escalation of care.
- **Patient experience measures** — Health-related quality of life (HRQoL) and psychological impact.

"Before investing, both payers and providers want a digital health tool to demonstrate its effectiveness and provide evidence that they can expect a return on their investment. A framework that establishes clear criteria to assess the value of AI tools will help healthcare organizations make decisions investing in, reimbursing for, and scaling certain technologies." [261]

— Consumer Technology Association

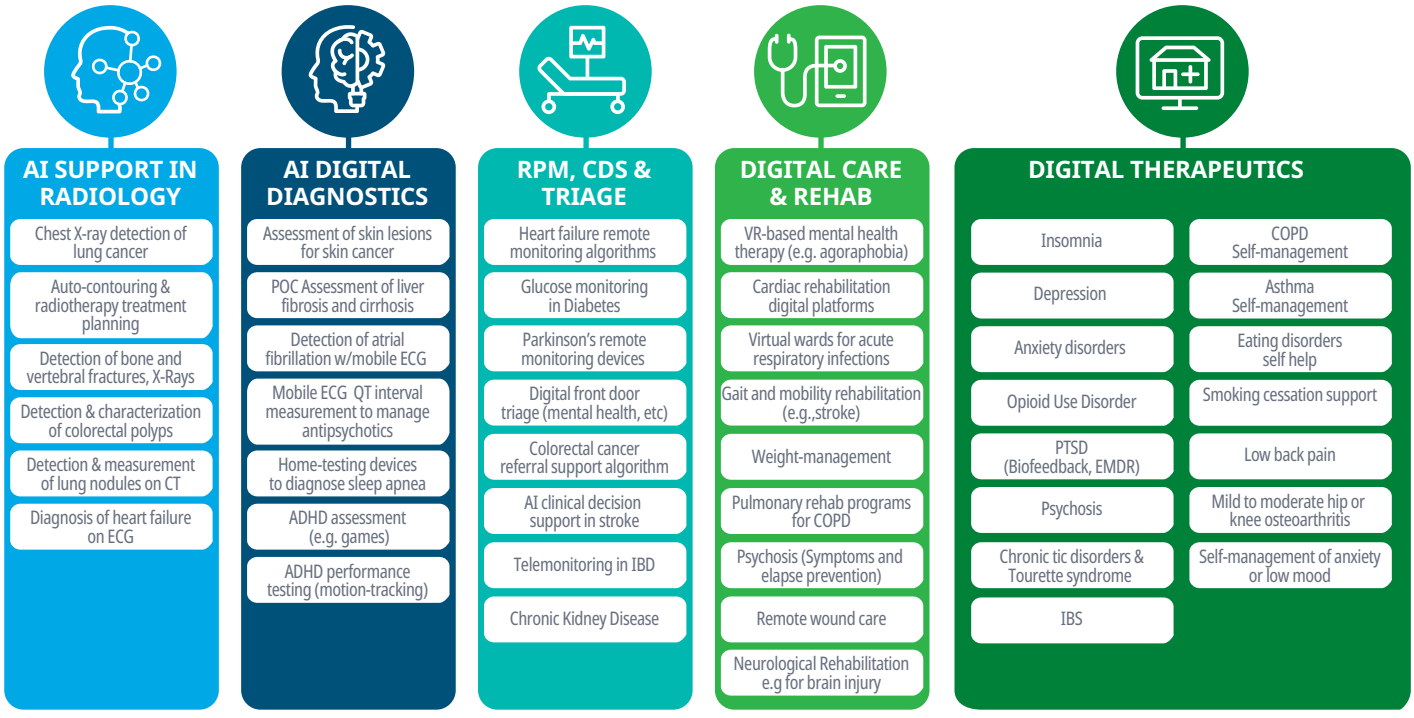
USE CASE MATURITY

As various health organizations begin to issue health technology assessments of digital solutions, it is becoming clearer where they have begun to find a foothold in care settings. Based on published guidance, the following use cases for digital tools can be considered the most mature and are areas where digital health solutions are beginning to impact patient care (Exhibit 44).

As health technology assessments have grown, it is becoming clearer where solutions are delivering and where they fall short. For instance, four recent assessments of digital health technologies conducted by the Peterson Health Technology Institute (PHTI) in the U.S. discussed how effectiveness varied by solution type and application (Exhibit 45).[262–265]

Common themes that emerged across assessments included the limited availability of long-term outcomes data and peer-reviewed randomized controlled trials necessary to evaluate clinical effects, as well as specific

Exhibit 44: Guidance topics as an indication of use case maturity



Source: IQVIA Institute Oct 2025. NICE Guidance Resource Planner; Oct 2025. Digizo.nu, Process Finder, Oct 2025; Peterson Health Technology Institute assessments.

Notes: Virtual Reality (VR); Attention deficit hyperactivity disorder (ADHD); Point-of Care (POC); Chronic Obstructive Pulmonary Disease (COPD). Eye Movement Desensitization and Reprocessing (EMDR). Post Traumatic Stress Disorder (PTSD). Remote patient monitoring (RPM). Clinical decision support (CDS).

Exhibit 45: Benefits and limitations of digital solutions assessed by Peterson Health Technology Institute

Depression and anxiety

- Blended-care models offer the most consistent clinical benefit
- Self-guided tools show lower engagement and durability
- Prescription digital therapeutics (PDTs) show stronger clinical evidence but are costlier
- Dropout rates are high, limiting long-term effectiveness
- Equity gaps persist; many tools are not designed for diverse populations
- Few published peer-reviewed RCTs
- Durability of effect is often unproven beyond 3–6 months
- Tools with coaching or therapist support show better adherence
- Cost-effectiveness is strongest for tools that reduce in-person therapy needs

Hypertension

- Medication management tools deliver rapid and clinically meaningful improvements vs. usual care
- Both behavior change and blood pressure monitoring approaches show limited clinical benefit
- All solutions increase short-term costs.
- Medication management solutions may offset and reduce long-term healthcare costs from cardiovascular events
- Blood pressure monitoring tools alone do not improve outcomes significantly
- Behavioral coaching tools have weak evidence of effectiveness
- Integration with primary care teams and usual care is often insufficient, limiting effectiveness
- Cost-effectiveness depends on long-term adherence and risk reduction
- Virtual care teams accelerate improvements vs in-person visits

Musculoskeletal

- Virtual MSK tools improve pain and function for many users
- Physical therapist-guided solutions are most effective with comparable or incremental outcomes vs. in-person PT
- Guided tools may reduce unnecessary imaging or surgery, but more evidence needed
- App-based exercise tools are cost-effective for low-acuity patients but only improve pain not function making in-person PT a better option
- Remote therapeutic monitoring tools improve adherence but increase costs
- Access gaps are reduced, especially for rural and older populations
- User engagement is higher with therapist involvement
- Evidence quality varies widely by vendor
- Observational studies predominate and many had medium-high risk of bias

Diabetes

- Most digital diabetes tools do not deliver meaningful clinical benefits
- Glycemic control improvements are minimal and short-term
- Remote monitoring and behavior change tools increase healthcare spending
- Nutritional ketosis tools show promise for diabetes remission
- Cost-effectiveness is poor for most tools
- HbA1c improvements are small and not durable
- Tools for newly diagnosed or insulin-starting patients may be more effective
- Behavioral tools are not effective as standalone interventions
- Ketosis-based tools may reduce medication use

Shared conclusions

- Many solutions lack robust, peer-reviewed randomized controlled trials (RCTs), and long-term effectiveness is often unproven
- Most tools are not well-integrated into primary care or broader healthcare systems, which can hinder effectiveness and data sharing
- Digital tools tend to be more effective for mild to moderate conditions
- Success closely ties to how actively users engage with the tools
- Equity and access gaps persist
- Behavioral tools are more effective when used as adjuncts or with professional guidance while many standalone tools show limited benefit
- Pricing and transparency around pricing models vary widely making it difficult for payers and employers to assess value and cost-effectiveness depends on price
- Outcomes are frequently self-reported, which may affect reliability

Source: Peterson Health Technology Institute Health Technology Assessments, 2024 through-mid 2025. Available from: https://phti.org[262-265]

features that influence solution effectiveness. Notably, solutions tended to yield improved outcomes when they incorporated blended-care models, employed stepped-care approaches that aligned patients with appropriate interventions, and when patients demonstrated higher levels of engagement and adherence. These design elements are already increasingly informing future care models. Digital health tools were also generally also found to be more effective for mild or low-acuity conditions than for severe symptoms and those focused on behavior change showed greater clinical value and efficacy as adjuncts to professional guidance than as standalone tools.

The assessments also revealed barriers that constrain impact, such as inadequate integration with healthcare systems and inconsistent data sharing with providers, as well as pricing. Financially, digital solutions often led to increased short-term costs but, when priced appropriately, could generate long-term savings by mitigating risk and preventing care escalation. However, existing pricing structures inconsistently reflected their actual clinical value, highlighting the potential of value-based pricing models to better align cost with outcomes and support broader adoption.

Drivers and barriers to adoption

+ **Integrating complex digital health solutions into care requires creating value for every stakeholder in the health ecosystem, making it essential for developers to understand each partner's multi-dimensional needs.**
+ **Although adoption of digital solutions has increased in countries with mature digital health policies, elsewhere the use of digital therapeutics and their integration into traditional care models remains limited.**
+ **Providers recognize that digital therapeutics offer potential benefits such as improved patient engagement, monitoring, and reduced care stigma but cite the need for stronger clinical credibility and evidence and uncertainty about reimbursement and how patients with adapt to the new experience.**
+ **The emergence of digital care programs delivered via telehealth is a key driver of adoption, with providers increasingly referring patients to rehabilitation and disease management programs rather than adopting standalone solutions themselves.**
+ **Pilot studies and pragmatic trials help gain clinician buy-in and demonstrate value. Provider workload concerns necessitate solutions that seamlessly fit into clinical practice without adding burden**
+ **Health system integration is likely to be a critical success factor as products are expected to be interoperable with electronic health records (EHRs), integrate seamlessly into existing workflows, facilitate billing and fit within traditional care pathways.**

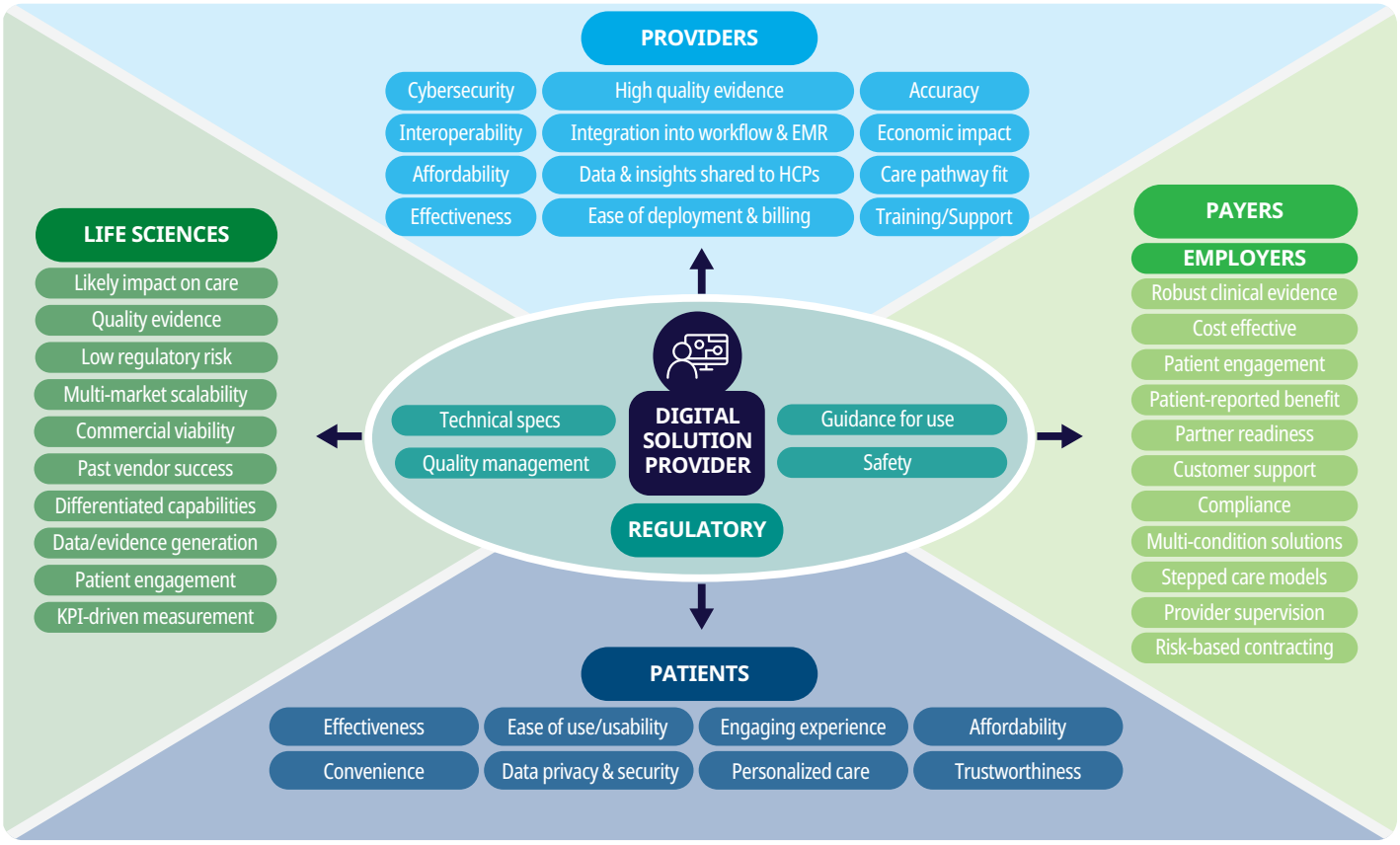
Even if digital health products successfully acquire payer coverage, they may still need to overcome adoption barriers among patients and healthcare professionals to become mainstream tools and scale in the market. Though the pandemic accelerated user familiarity and comfort using digital tools, it can still take a long time to integrate new technologies and new therapies into traditional care models. Mature national policies have helped to increase adoption and prescribing of digital therapeutics in some countries, but in others use of digital therapeutics and other digital tools have a long way to go.[1]

STAKEHOLDER REQUIREMENTS

For each type of digital health solution and business model, the stakeholders influencing adoption vary. However, more complex and integrated care solutions — those that embed into customers' lives and the broader healthcare ecosystem — typically require buy-in from a wider range of health system partners. This poses a challenge for developers to demonstrate value to each of them. Across the ecosystem, stakeholders differ in their goals for digital solutions and their vision for how these tools should fit into or evolve the current state (current life, care pathways) shapes how they assess solution value. Understanding these perspectives can help developers meet the diverse needs and requirements of each stakeholder and build solutions that resonate across the ecosystem (Exhibit 46).

For instance, a digital therapeutic will need to meet the evolving evidence requirements of regulatory agencies and demonstrate cost effectiveness to payers but also needs to be designed so the patient finds it easy to use and engaging, and health system expectations for integration and interoperability are met. Providers and health systems may be eager to adopt care innovations, but if a solution cannot integrate with EHR systems, fit within traditional care pathways, be billed, or is too costly, it may be difficult to secure a champion to pilot or scale the product. Meeting end-user needs can also accelerate adoption. An IQVIA Institute study found that

Exhibit 46: Stakeholder requirements for digital solutions to access various revenue streams



Source: IQVIA Institute; Jul 2025; IQVIA Integrated Digital Health and MedTech Consulting.

mobile health apps with a store rating of 4.8 were adopted 11-times faster than those rated 4.6, based on downloads.[1]

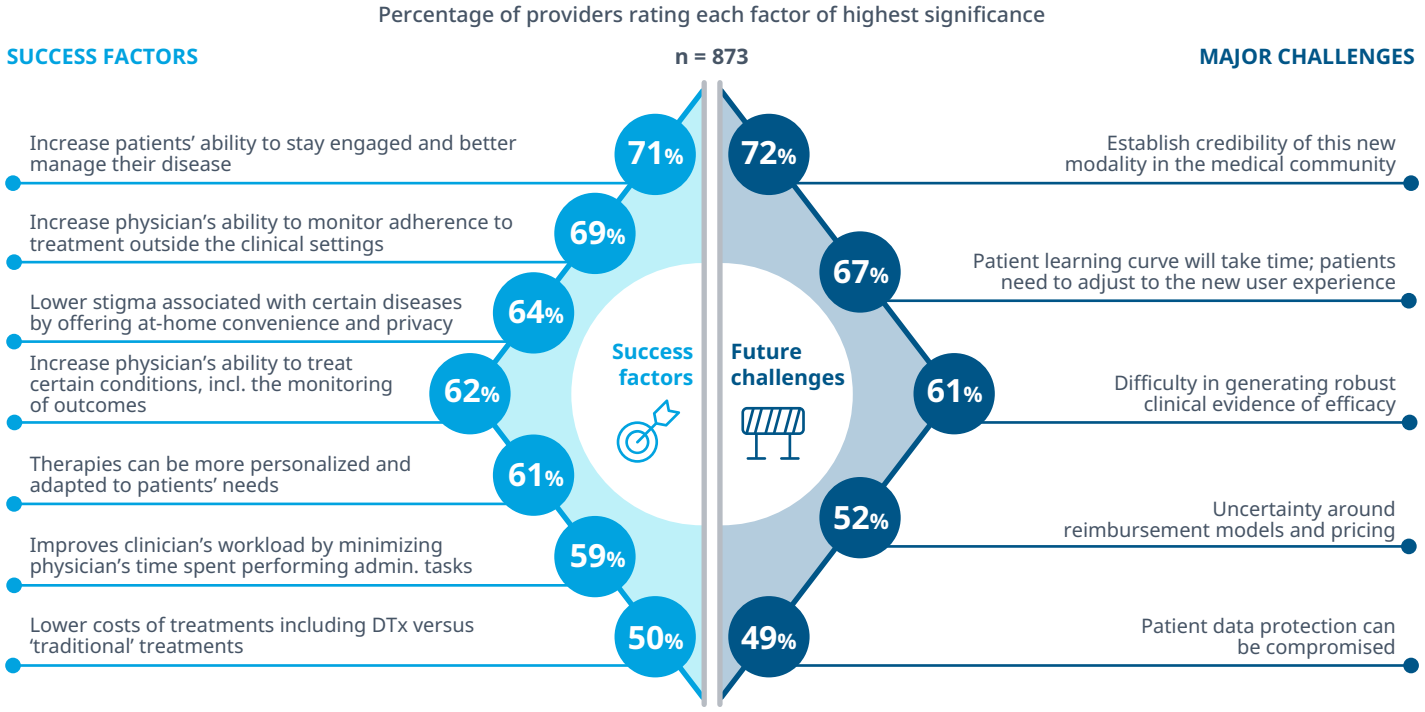
PROVIDER AND HEALTH SYSTEM NEEDS

Digital therapeutics

A multi-country IQVIA study of healthcare provider adoption conducted in 2023 (see Methodology, IQVIA Multi-Country Remote Care Study) found that while providers believed Digital Therapeutics could improve patient management — by keeping patients engaged, supporting follow-up outside the clinical setting, and reducing treatment stigma — they still lacked confidence in their use.[266] Overall, 72% of healthcare professionals cited establishing credibility in the medical community as the greatest remaining hurdle, pointing to gaps in evidence generation (Exhibit 47). Neurologists emphasized the lack of robust clinical efficacy data, while general practitioners were more concerned about the patient learning curve.

The credibility barrier has been addressed to some extent in countries with mature assessment pathways, by providing a centralized repository of clinical evidence for reimbursed solutions. For instance, the Germany's Digitale Gesundheitsanwendungen (DiGA) directory describes the clinical evidence generated on each listed digital therapeutic, helping to drive uptake in these geographies. In the UK, where NICE guidance already provides a robust review of evidence for providers, the NHS's new 10-Year Health Plan for England also plans a 'HealthStore', where patients will be able to access approved health apps to manage or treat their condition.[50]

Exhibition 47: Success factors and challenges for Digital Therapeutics in the coming years: The provider's view



Source: IQVIA; Multi-Country Remote Care Focus Pilot, April–June 2023.

Notes: Displays the percentage of HCPs rating each success factor and challenge for Digital Therapeutics of highest significance in the coming years. Values are the proportion of doctors having provided an answer of 4 or 5 in each category. Questions were: "In your opinion, what could be the major success factors of Digital Therapeutics in the coming years? Please rate on a scale of 1–5. and "In your opinion, what are the major challenges that Digital Therapeutics will face in the coming years? Please rate on a scale of 1–5." A total of 1594 responses were received across 11 countries with 140–147 responses per country, and 873 responses to these questions. Sample includes only General practice (except in JP), Internal Medicine (JP only), Pediatrics, Neurology, Psychiatry.

> *"We will build a new 'HealthStore', which will… get new digital tools directly into the hands of those who need them…" New apps will become available regularly, across different condition areas … accompanied with a recommendation from a clinician to use the technology. Patients will be able to choose which tool best suits them, when there is more than one option."* [50]
>
> *— FIT FOR THE FUTURE 10 Year Health Plan for England*

The study also found that more than half of providers expressed uncertainty around solution cost and reimbursement, which is unsurprising given that reimbursement for clinical services may still be limited in some geographies.[248] This highlights how important it is for solution developers to educate providers and guide them through reimbursement processes as opportunities emerge. That could include helping providers meet national eligibility requirements, offering clear billing guides with associated codes, or even embedding billing modules directly into the solution.

"Our goal is to link all digital therapeutic devices to a telemedicine consultation platform, which we are working on as a national project… Telehealth should be the foundation for patients and physicians to utilize digital healthcare." [248]

— Shin Jae-yong of Preventive Medicine at Yonsei University College of Medicine, South Korea

Interestingly, in countries where providers may have had the most experience, like Germany and France, success factors were rated lower and challenges as more significant than those countries at early stages of penetration where providers are likely to have less experience. This may indicate that as digital health solutions enter practice, the promise and hype/ excitement moderates once realistic challenges are seen, such as difficulties integrating solutions into care or existing systems.

Indeed, health system integration is increasingly a critical success factor for digital health adoption. Care organizations now expect developers to ensure interoperability with electronic health records (EHRs) and billing systems, and to ensure data flows into patient health records — returning actionable insights to providers. This functionality helps deliver value to providers and health systems, strengthening the case for adoption. Providers' growing workload is both a driver of adoption and a concern. While digital health solutions have the potential to improve provider workload and efficiency, tools that are poorly designed or poorly integrated into clinical practice, risk adding to the burden providers already face. For instance, point solutions that entered the market early threatened to add a panoply of separate apps and systems for normal providers to manage. It is now clear that provider-focused solutions — including digital diagnostics, clinical decision support tools, remote patient monitoring, and AI-enabled platforms — need to avoid contributing to this burden and instead align with existing workflows, eliminating the need for separate or bespoke processes.

The emergence of "digital-first" care providers who view digital innovations as core to their practice has also helped to drive adoption of digital solutions. Digital care providers may own software-based tools and center them within commercially marketed physician and/or coach-supported disease management programs that span prevention, diagnosis, treatment, disease self-management, and monitoring. In the United States, for instance, traditional providers increasingly refer patients to dedicated digital-first care programs for rehabilitation and disease management, rather than adopting digital solutions themselves. Select health systems have alternately opted to adopt innovative "blended care" models using digital tools that help differentiate their care offerings as cutting-edge. One example is Mt. Sinai's use of MindMotion GO — a virtual reality game for neurological rehabilitation that helps stroke patients recover physical movement. Through this partnership, Mount Sinai created an innovative, digitally enabled program that extends into the home setting: Mount Sinai's MindMotion GO telerehabilitation program.[284]

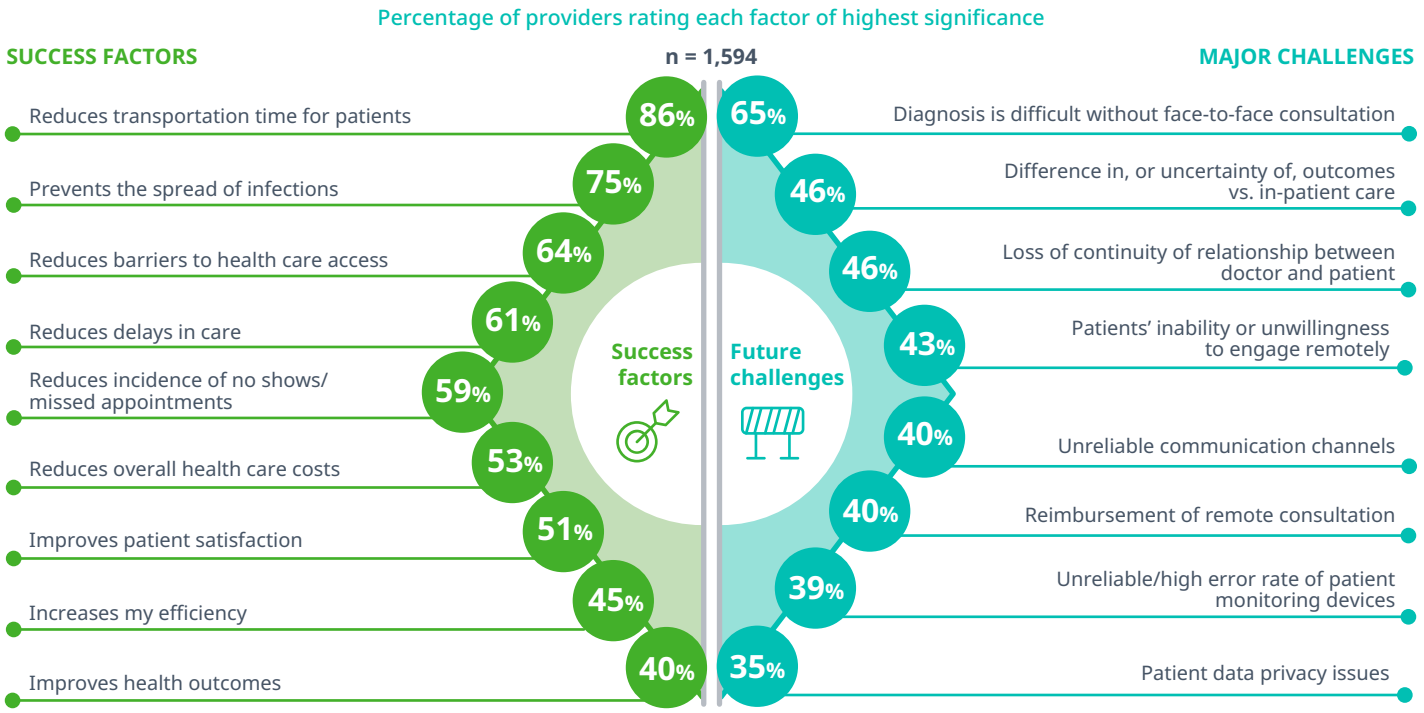
In other countries, the intent is for traditional care providers and models to evolve to incorporate digital tools. For instance, in the UK, already a third of mental health treatments (talking therapies) delivered by the NHS are delivered online rather than face-to-face.[267] While some of these are pure telehealth sessions for patient with mild to moderate depression or anxiety, in some they can be assigned to app- or web-based digital therapeutics including self-guided cognitive behavioral therapy (CBT) courses.[268]

Finally, to gain clinician buy-in, pilots and pragmatic trials are often needed, helping to build provider familiarity with the technology and understand how their specific populations might benefit.

Remote Patient Management

The set of benefits and challenges that providers associate with remote patient management and telemonitoring tools differs from those linked to digital therapeutics. Providers expect remote care to reduce patient transportation time, improve access, and limit the spread of infections (Exhibit 48). However, their concerns center on the risks posed by reduced face-to-face contact and the absence of in-person examinations, which may affect diagnostic accuracy and the patient-provider relationship. The largest share of providers cited concerns about diagnosing patients without direct contact, followed by potential impacts on patient outcomes and how remote communication might hinder their ability to engage with patients and maintain strong relationships.

Exhibit 48: Success factors and challenges for Remote Patient Management in the coming years: The provider's view



Source: The remote healthcare revolution: An investigation into HCPs' perceptions of the evolving digital landscape– Part 1: Telemedicine, Jan 2024. Available from https://www.iqvia.com/blogs/2024/01/the-remote-healthcare-revolution-part-1. IQVIA; Multi-Country Remote Care Focus Pilot, April–June 2023

Notes: Displays the percentage of HCPs rating each success factor and challenge for Digital Therapeutics of highest significance in the coming years. Values are the proportion of doctors having provided an answer of 4 or 5 in each category. Questions were: "4. In your opinion, what are the major success factors of remote patient management? Please rate on a scale of 1-5. and "In your opinion, what are the major challenges you face in the management of patients remotely? Please rate on a scale of 1-5." A total of 1594 responses were received across 11 countries with 140–147 responses per country. Sample includes only General practice (except in JP), Internal Medicine (JP only), Pediatrics, Neurology, Psychiatry.

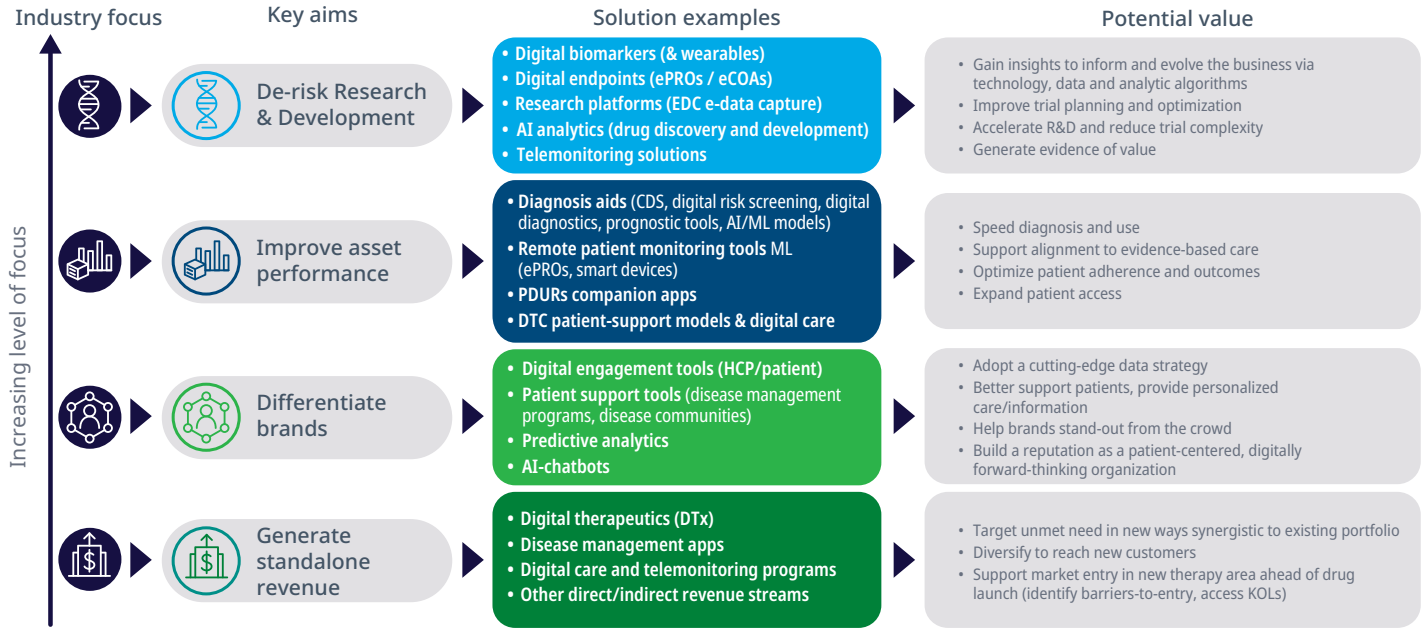
Life sciences opportunities and partnerships

+ **Leading life sciences companies now take a systematic approach to digital health investment, conducting portfolio-wide value and feasibility assessments that span solution types to ensure digital initiatives are impactful.**
+ **Digital tools are used across the lifecycle of medicines to de-risk clinical development, differentiate brands and improve their performance in the market, and increasingly fill portfolio gaps and address unmet patient needs.**
+ **Through partnerships with device makers, sensor-enabled monitoring devices are being used in clinical development to create more precise endpoints that can accelerate trials and reduce costs.**
+ **FDA's draft guidance on Prescription Drug Use-Related Software (PDURS) has also renewed interest in digital solutions that deliver value beyond the pill by offering a lower-risk path to launch software alongside therapies.**
+ **To improve patient access to medicines, companies are building patient support ecosystems and branded platforms through partnerships with telehealth providers, online pharmacies, labs and other digital service providers.**
+ **Life sciences companies partner with digital health solution providers to co-develop innovative offerings, while device manufacturers may seek out local life sciences firms to help them enter new markets — particularly in Japan.**
+ **To overcome market barriers for digital solutions, life sciences companies are adapting go-to-market strategies from traditional medicines — preparing the market for launches and leveraging data to guide rollout and monitor adoption.**

NEW DEVELOPMENTS

Life sciences companies have predominantly looked to digital health products to add value across the traditional lifecycle of medicines (Exhibit 49).

Slide 49: Focus of digital health and data investment by life sciences companies



Source: IQVIA Institute; Sept 2025. IQVIA Integrated Digital Health and MedTech Consulting.

Notes: Electronic data capture (EDC). Clinical decision support (CDS). Prescription drug use related software (PDURS). Remote patient monitoring (RPM). Key opinion leaders (KOLs).

Software-based tools, sensor-based monitoring devices and the data they deliver are being used to enhance disease understanding, de-risk clinical development and improve the market performance of existing and investigational medicines. More recently, standalone solutions like digital therapeutics are being used to target unmet need.

De-risk clinical development

During the COVID-19 pandemic, life sciences companies mitigated clinical development risks by adopting decentralized and hybrid trials that leveraged digital technologies. While many have since returned to site-based studies, digital solutions remain central to improving measurement and optimizing research. Leading companies have built molecule-to-market digital strategies for their clinical development trials that rely on connected devices and wearables to collect sensor-based measures and app-based remote monitoring tools to track health outcomes (ePRO, eCOA).[1]

This investment has been driven by the potential of continuous data collection to generate more precise endpoints, which can accelerate trial timelines or reduce costs. Additionally, new measures that capture nuanced aspects of the patient experience in daily life can reveal the therapeutic value of investigational products and help differentiate them once they hit the market.[1] Remote monitoring of patients in trials and post-market care settings also offers the potential to manage health risks and may enable higher-risk drugs — particularly in oncology — to reach the market by helping offset adverse events.[1]

This trend has opened opportunities for life sciences companies to partner with device makers, using their data collection tools and platforms in clinical trials to create and validate new digital measures. For example, Bayer partnered with Samsung to use its platform and wearables to track sleep disturbances during menopause (SDM), while Sanofi used a wearable sensor

SIMPLIFYING DATA COLLECTION FOR DIGITAL SOLUTIONS

Research and development trials involving digital tools place a uniquely high burden on clinical sites and patients. As digital therapeutics and digital measures proliferate in R&D trials, site staff must navigate multiple interfaces and sometimes manually link data. For example, in trials using sensors and wearables, digital biomarker and endpoint data must be integrated with electronic medical records (EMRs), claims data, and other sources to ensure clinical and research relevance. Staff often undergo extensive training to distribute, link, and support these tools, but the process still raises workload and the potential for error.

Patient participation may also become more complex by adding the need to copy activation codes from emails, re-enter personal data already held by the site (e.g., gender, age, birthdate) and new login credentials to remember. Additionally, the use of digital therapeutics (DTx) and tools that record patient endpoints — such as electronic patient-reported outcomes (ePRO) and electronic clinical outcome assessments (eCOA) — may require patients to manage multiple usernames, passwords, and apps throughout the study.

To reduce complexity and burden for trial participants and staff, automated data collection and integration strategies are increasingly vital. These simplify processes and minimize manual steps and errors when integrated into existing physician EMRs and patient mobile workflows. Integrated technology solutions, such as AppScript OneClick Studies, that enable electronic data capture and automatic EMR-to-EDC flow can streamline data collection, linkage, and task management within clinical workflows, ultimately reducing burdens for both site staff and patients.

and app to measure how scratching affects sleep in atopic dermatitis. Bluerock and others have explored motor symptoms, sleep, and balance in Parkinson's disease.[268–270] Companies may also collaborate with telemonitoring providers — such as Hospital at Home and Virtual Ward technologies — to track meaningful changes in symptoms.

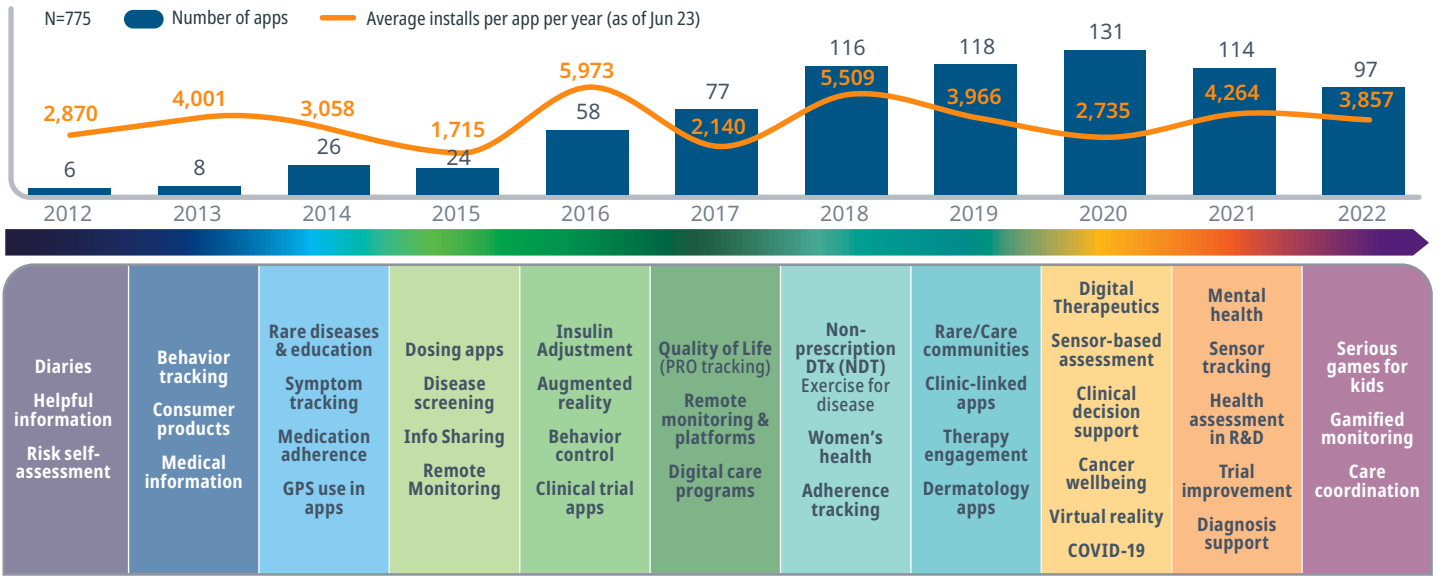
Improve asset performance

Life sciences companies — including those developing biopharmaceuticals, medical devices, and consumer health products — have steadily invested in more sophisticated digital solutions over time, including nearly 800 consumer apps launched between 2011 and 2022 (Exhibit 50). Early efforts focused on creating value "beyond the pill," and aimed to improve patient engagement and support clinicians. However, as new approaches and capabilities evolved, these patient apps evolved from basic educational tools (e.g., drug and disease information, demonstration videos) to platforms that promoted engagement and adherence (e.g., diaries, behavior tracking, reminders), to apps with more advanced functions such as non-prescription digital therapeutics (NDTs), disease support apps and ones focused on remote patient monitoring.

Although their overall number of new app launches declined in 2022, the U.S. FDA's draft guidance on Prescription Drug Use-Related Software (PDURS), issued in September 2023, prompted life sciences companies to revisit "beyond the pill" strategies. Under this framework, digital apps can be paired with drugs to enhance adherence, safety, and efficacy by offering personalized dosing, behavioral support, disease education, or symptom monitoring.[107] Initially, many companies feared that in order to make health claims about an app's benefit, they would be required to submit the software as part of the new drug application (NDA), potentially complicating approval. However, PDURS guidance clarified that software can be submitted via supplemental NDAs (sNDAs) and still be referenced on the drug's label. This has reduced regulatory risk and renewed interest in partnering with developers of therapeutic and patient support platforms to improve outcomes.

Partnerships have also focused on building direct-to-consumer (DTC) platforms to engage patients and tailored patient support solutions, creating opportunities for telehealth companies and digital care providers. For example, Biogen partnered with Happify

Exhibit 50: App investment and innovation by life sciences companies over time



Source: Adapted from: Digital Health Trends 2024: Implications for Research and Patient Care. IQVIA Institute for Human Data Science, December 2024.

(now Twill) to customize the Kopa care community platform for multiple sclerosis (Kopa for MS), offering education and mental health support.[271] And, as virtual care providers demonstrate their ability to expand access, life sciences companies and digital developers have shown growing interest in partnering with telehealth providers to accelerate patient access, as Axena did with Leva.[33] These patient support solutions have become more comprehensive, with some life sciences companies establishing branded ecosystems — such as LillyDirect and Pfizer4All — that enable patients to receive care through a digital front door.[272] These platforms connect patients to a network of partner services, including telehealth providers for prescription access, laboratories, online pharmacies for fulfillment, and digital care services for wraparound patient support. The aim to deliver a consumer-friendly, Amazon-like end-to-end experience reflects a paradigm shift toward integrated platforms that support the full patient journey, including seamless copay assistance.

Another area of keen interest for life sciences companies and other stakeholders has been provider-focused digital solutions including those that can expand the use of traditional medicines. Partnerships between life sciences companies and digital developers have led to the co-creation of tools that not only support clinical decision-making but also extend care beyond the clinic — enhancing diagnosis, engagement, and outcomes across the patient journey. These include solutions that may pre-screen patients to accelerate diagnosis and align care to evidence-based guidelines. For instance, partnerships with developers may focus on AI-enabled digital solutions like clinical decision support (CDS) tools, which help providers make evidence-based decisions during diagnosis, treatment, and prevention.

These tools are especially valuable in complex or rare disease contexts, and their appeal has grown as FDA guidance exempts true CDS tools (meeting criteria) from regulatory approval.[1] However, partnerships opportunities also extend to AI-based digital diagnostics, which can facilitate wide-population screening, enable at-home self-testing, and support primary care providers in assessing specialty conditions at the point-of-care. These tools include tools for trials and risk screening, prognostic tools and For example, Bayer partnered with Huma Therapeutics to launch a heart disease screening tool on the Bayer Aspirin website, helping users assess cardiovascular risk and share results with their physicians and also collaborated with Ada Health to embed its AI-powered symptom assessment chatbot into several consumer health brands, enabling users to better understand symptoms and potential treatment options.[1,273]

Standalone revenue opportunities

Increasingly, digital health devices like digital therapeutics are also seen as tools that, themselves, can improve health outcomes for patients receiving therapies — for instance improving patient self-care or addressing unmet needs by treating disease via new mechanisms. This has made digital therapeutics and other mobile tools a focus of renewed attention to help round out therapeutic portfolios and diversify income streams. After initially stepping away from building proprietary digital solutions, companies are now actively partnering with leading digital health developers.

These partnerships allow life sciences firms to address unmet needs in ways synergistic with existing portfolios and diversify their portfolios to reach new customer segments — sometimes in advance of a drug launch in a new therapy area, helping to identify market barriers and engage key opinion leaders (KOLs)

Finally, diagnostics companies are also evolving their offerings to include software-based analytics. Roche Diagnostics, for example, is building a platform of digital diagnostic algorithms, including the FDA-authorized Sepsis ImmunoScore developed by Prenosis. This AI-driven tool helps providers identify patients at risk of sepsis within 24 hours and integrates with electronic medical records (EMRs).[274]

Expanding digital therapeutics reach through co-promotion

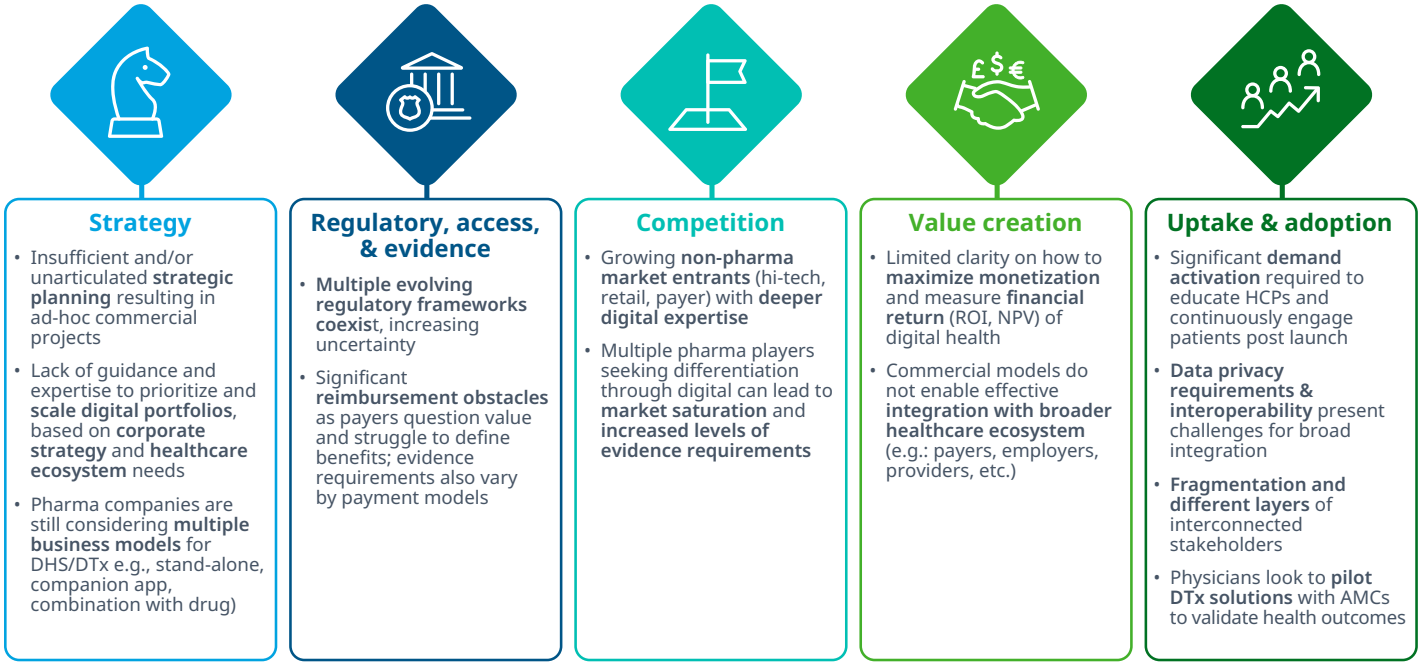
Life sciences companies may prove especially valuable as partners in launching already-marketed digital products in new geographies. Although there was excitement in the industry early on that life sciences companies might bring their experience, capital, and skills to bear marketing digital health products, such excitement waned after Novartis/Sandoz's co-promotion of Pear Therapeutics digital therapeutics ended.[275]

However, as pharmaceutical heavyweights show renewed interest in partnering with leading digital developers (some of which have successfully launched multiple products), this has also reopened the possibility that life sciences companies may decide to promote digital solutions in the future. In Japan, for instance, where product distribution may be strongly dependent on hospital and other medical institutions, co-marketing agreements with life sciences have already re-emerged. Teijin Pharma has promoted CureApp's hypertension digital therapeutic, CureApp HT, to medical institutions since April 2024 with a sales force of around 1,000-people, and Sawai Pharmaceuticals now markets CureApp AUD.[276–278] Development of the pediatric ADHD digital therapeutic EndeavorRIDE for the Japanese market also occurred through Akili's (now Virtual Therapeutics') collaboration with Japan-based Shionogi,[279–281] and Rejoyn for major depressive disorder in the United States, was developed through a joint partnership between Japanese company Otsuka Pharmaceutical and Click Therapeutics. Susmed's has also formed a sales partnership with Shionogi for Medcle.[232] As many of the first solutions flowing through pathways in Japan — and similarly in France and Korea — have been home-grown in their respective countries, having a local partner to facilitate entry is likely to be a helpful factor more generally.

BARRIERS TO SUCCESS

Despite the continued interest and promise, several challenges remain for life sciences and other digital developers to unlock the full potential of digital health solutions (Exhibit 51). While many of these have prevented adequate commercial uptake, leading companies are now taking a more systemic approach to product development, selecting partners with proven capabilities, and applying their expertise to achieve commercial excellence.

Exhibit 51: Challenges facing life sciences companies commercializing digital health



Source: IQVIA; Oct 2025

SUCCEEDING IN PARTNERSHIP MODELS

Ensuring a digital health product achieves its intended portfolio aims depends on a clear, end-to-end strategy — executed quickly, thoughtfully, and with the right partners. To accomplish this, leading life sciences organizations have begun applying the same disciplined and systematic approach they have long used for traditional therapeutics, to the digital space. Focusing their resources on the most impactful digital initiatives, they are leveraging data to guide strategy, identify opportunities and learn from digital health organizations that have successfully scaled. These insights help ensure partnerships are grounded in real-world demand and positioned for success.

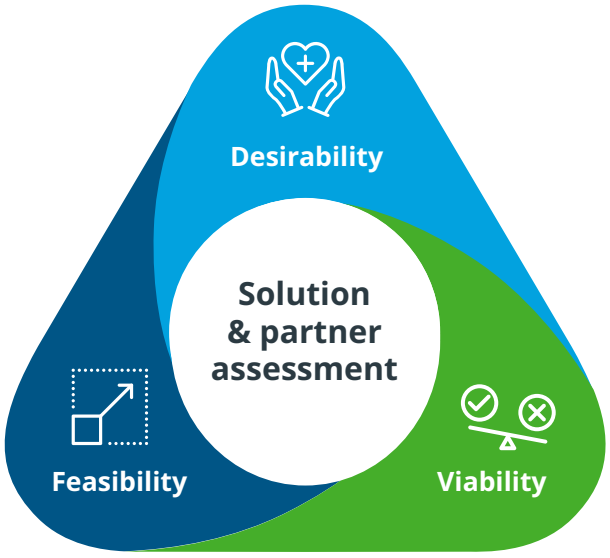
Company structures

Previously, life sciences teams responsible for digital excellence were often dispersed across business units, global and regional groups, and commercial innovation or technology-focused functions. Some large organizations have since centralized these efforts within digital innovation labs to streamline product ideation, development, and deployment — to avoid duplicating effort, reduce cost inefficiencies, and better manage risks to the business. Yet both models were perceived to result in siloed teams creating solutions that failed to address critical challenges tied to asset and portfolio brand strategy. Pharma companies continue to refine organizational structures and are increasingly adopting smaller, agile teams that lead cross-functional processes across global and local business units to secure organizational buy-in and strategic alignment on digital initiatives. Once that alignment is achieved, companies may then determine whether to build, buy, or partner.

Need identification

As digital capabilities mature, this more centralized approach has led life sciences companies to take a more structured and systematic approach to evaluating digital health investments. With multiple product types now available to intervene at different points along the patient journey and address care gaps, companies conduct portfolio-wide assessments of solutions spanning the continuum — from pre-diagnosis to therapy initiation to monitoring. These assessments identify where digital tools can solve specific portfolio challenges or enhance brand performance.

Exhibit 52: Evaluating solution value and partner fit



Desirability
focuses on whether the solution / partner meets the needs and desires of company's patients

Feasibility
assesses whether the solution can be realistically implemented with the available resources and technology

Viability
examines whether the solution is sustainable and aligns with the company's business and product goals

Illustrative evaluation criteria (non-exhaustive)
• Pain point is considered critical by patients and providers
• Extent to which pain point is solved by the partner's solution
• Degree to which solution enhances user experience
• Technical feasibility for availability by launch (for company products)
• Infrastructure maturity and ability to integrate into company's network
• Regulatory, legal and compliance complexities/ and requirements
• Scalability
• Partner maturity and proven outcomes
• Solution process moves towards product goals
• Development and maintenance cost
• Fit with company's strategic imperatives
• Applicability across company's potential portfolio

Source: IQVIA Integrated Digital Health; Oct 2025.

This includes pinpointing scenarios where a product could activate target patient segments, raise awareness, improve access, or address unmet needs. Companies then apply rigorous, consistent frameworks to evaluate the potential desirability (impact/value), feasibility and commercial viability of each option, narrowing their focus to the most promising product profiles (Exhibit 52).

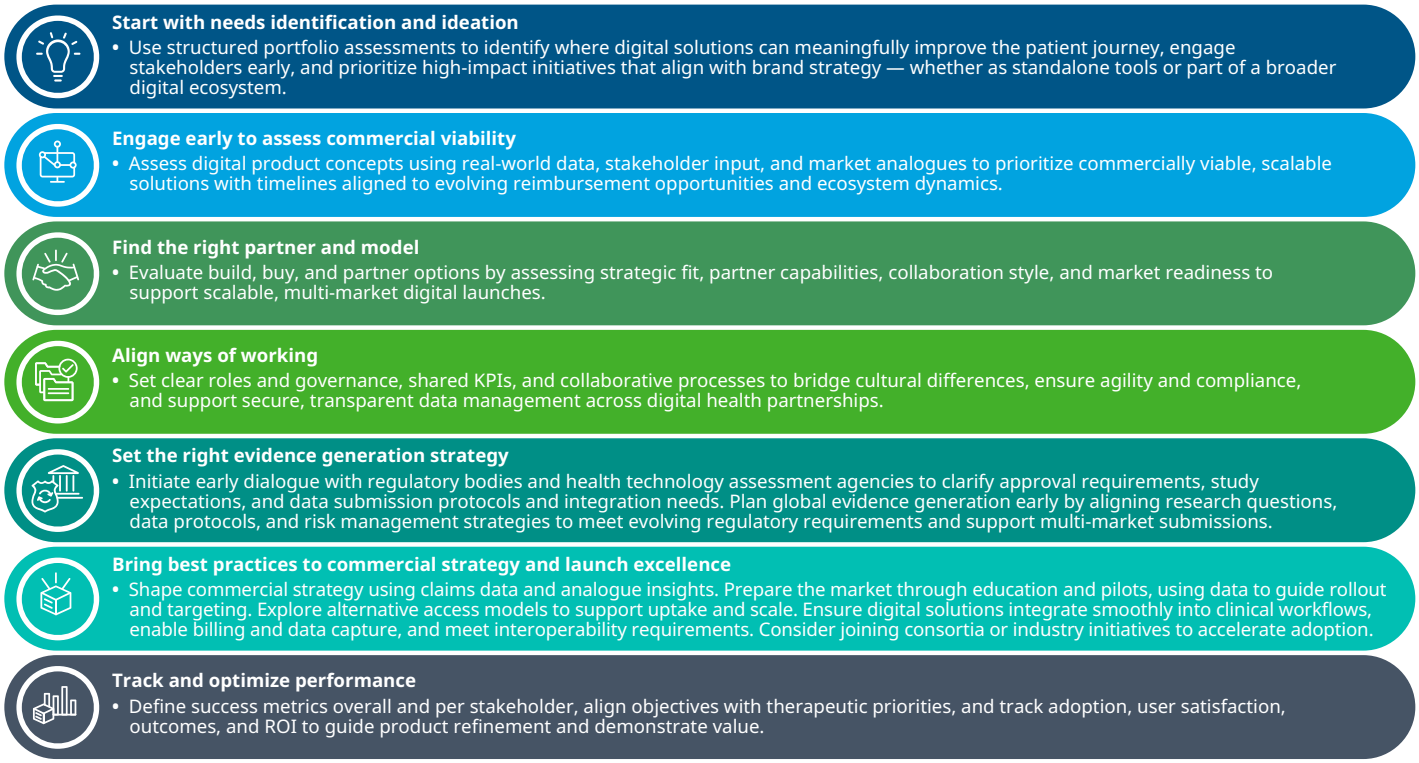
This process ultimately makes it easier to identify digital health partners whose offerings align with strategic goals and meet key requirements. A thoughtful assessment also helps avoid duplication and ensures digital health investments target areas where they deliver the greatest value. Scope matters as well: while standalone solutions address specific points in the patient journey and may support a single brand, digital platforms and storefronts may integrate multiple solutions within a pharma-branded digital ecosystem to solve problems more holistically.

Ideation approach and product refinement

Engaging internal teams and external stakeholders early in the ideation process helps to shape digital health solutions and can significantly influence their success in the market (Exhibit 53). Input from clinicians and patients helps to align products with real-world needs, and avoid adoption barriers and other commercial pitfalls, and ultimately determine whether a solution succeeds or fails. This principle underpins programs such as the FDA TAP advisory initiative, Digizo.nu in the Netherlands, the NHS Innovation Service and other national programs.[109]

This kind of early feedback can help developers refine their product and ensure their vision meets care needs appropriately. It can also help quantify likely impact on the patient journey — such as improvements in access, adherence, or outcomes — which can build internal alignment and support. When stakeholders see how a solution fits into broader care pathways, they are more likely to champion its development and adoption. For this reason, stakeholder narrative testing and early message development around unmet need, clinical benefit, and value can strengthen product positioning and improve buy-in.

Exhibit 53: Succeeding in partnership models



Source: IQVIA Integrated Digital Health Team; Oct 2025.

Commercial viability and ROI

Evaluating commercial viability is just as important for digital health solutions as it is for traditional medicines and helps companies focus their efforts where they're most likely to gain traction. Not surprisingly, life sciences companies building in this space have turned their focus to achieving excellence in commercialization in a disciplined way just as they have done with traditional medicines, examining data to understand where opportunities lie and exploring product analogues learn from digital health companies that have seen adoption and have scaled their solution. Landscape assessments covering both marketed products and pipeline solutions and forecasting and commercial assessments can provide valuable insights into the potential for digital solutions to meet key aims.

In the U.S., some companies have launched appeals to cash-pay customers through digital storefronts with discounted prices. However, it is also important for life sciences companies considering direct-to-consumer models to assess whether the potential market size and additional patient demand that might be gained justifies the scale of investment and understand the unmet patient need it addresses.

As funding and reimbursement pathways evolve, the potential return on investment for various product types will also shift over time. For this reason, the time horizon for solutions of various types to become scalable and economically sustainable needs to be considered alongside key product aims. Life Science companies developing digital solutions have often gravitated initially toward business models with lower regulatory barriers, however as digital tools become more integrated in care — via billing codes, policy shifts and the collective action of consortia — the value regulated devices can offer will grow, though it may take time to gain reimbursement. In the longer term, as reimbursement grows, this may shift the ROI further.

Evidence generation (regulatory)

Establishing clinical credibility for digital health solutions is a critical factor in product success. Planning out an approach that optimizes necessary clinical and real-world evidence (RWE) can help ensure that digital health solutions meet regulatory requirements. Defining research questions upfront and establishing clear protocols for consent, data privacy, and data management makes it easier to navigate regulatory pathways later on and help to encourage adoption and uptake of the solution. It's also useful to understand how risk management requirements vary across markets, for example with DCB0129 and DCB0160 in the UK. Conducting workshops to identify potential risks and develop mitigation strategies can help teams stay ahead of evolving regulatory and health system expectations. This proactive approach builds trust with stakeholders and supports smoother market entry. The approach to security also needs to be considered, with DiGA in Germany requirements to meet increased security standards set out in BSI TR-03161.

To support multi-market launches, companies are also increasingly developing global rollout strategies and regulatory and security strategies early in the product lifecycle, ensuring alignment across geographies and regulatory bodies. While there has been growing alignment on evidence requirements, as countries like Japan begin to offer financial incentives for early launch, ensuring opportunities aren't missed due to delayed studies becomes more important. Financial modeling to demonstrate cost-effectiveness across geographies is additionally becoming more critical for payers/purchasers as competition increases, making it important to have a plan to generate health economic studies.

Aligning ways of working

Establishing clear roles and governance structures is one of the most important steps in building successful partnerships between life sciences companies and digital health developers — ensuring both can operate together to efficiently adapt to evolving needs and deliver

measurable value throughout the collaboration. Early alignment on governance structures, with clearly defined roles, responsibilities, and decision-making protocols can help to ensure agility while maintaining compliance. Compared to the more iterative, fast-paced nature of start-up digital health innovators, pharmaceutical companies tend to have more structured, risk-averse processes to decision making that may take longer. Bridging these cultural differences can lead to more productive collaboration.

Dedicated alliance managers and project leads can help maintain coordination, while shared dashboards and KPIs provide transparency and accountability. Going beyond the regulatory approaches often specified in partnership agreements, it's also essential to set up risk management processes and define robust data governance policies from the outset, including how patient consent, data residency, and cybersecurity will be managed. Additionally, fostering open communication and planning to help solutions scale and maintain continuity during organizational changes is vital to sustaining momentum and deliver long-term value. This can help build trust and ensure long-term sustainability.

Rollout and Go-to-market strategy (market shaping, launch excellence)

Preparing the market for launch and developing a go-to-market strategy is just as important for digital health solutions as it is for pharmaceuticals. Strategies to overcome adoption barriers are critical in this early market. While pilot studies can help build familiarity and trust, and in theory, "samples" of standalone digital therapeutics can be offered to providers in the same way pharmaceutical products are (with targeting guided by data), partnering with virtual or digital care companies can also help overcome adoption issues.

Companies are also increasingly using uptake data to guide rollout plans, both locally and globally and developing implementation plans and go-to-market strategies. Claims and prescribing data can help track uptake of already-launched digital solutions and identify early adopters to help guide and tailor the rollout plan (both local and global) for new solutions. Especially when planning for multi-market launches, it is increasingly important to ensure a global product strategy is in place.

To support commercial viability, companies with recently launched products often file applications for billing codes to facilitate reimbursement and monitor market uptake, while also pursuing other strategies to optimize access. In this early market, making it easy for providers to prescribe a solution — by supplying clear instructions such as which billing codes to use or by building automated billing functions into platforms — helps overcome confusion and streamline adoption.

Ongoing management and KPIs

Finally, tracking performance within the partnership is essential to sustaining successful partnerships. Establishing clear metrics of success to measure at the outset — and per stakeholder — can make it easier to demonstrate value, identify gaps in performance early to guide product improvements or adjust strategies. Life sciences companies may want to monitor topline metrics such as investment levels, development and/or commercialization time, extent of global rollout, revenue or return on value as well as the time it takes to reach those targets. For instance, patient/user metrics worth tracking may include adoption (e.g., downloads, claims, prescriptions/referrals) and solution ratings/feedback alongside others relating to regulatory milestones and reimbursement, while cost effectiveness and health economic measures are important to payers/purchasers.

Notes on sources

THIS REPORT IS BASED ON THE IQVIA SERVICES DETAILED BELOW:

IQVIA's LONGITUDINAL PRESCRIPTION DATA

IQVIA receives nearly 4 billion prescription claims per year with history from January 2006 with coverage over 90% for the retail channel, 60–85% for mail service, and 75–80% for long-term care. Longitudinal data derives from electronic data received from pharmacies, payers, software providers and transactional clearinghouses. This information represents activities that take place during the prescription transaction and contains information regarding the product, provider, payer, and geography. Rx data is longitudinally linked back to an anonymous patient token and is linkable to events within the data set itself and across other patient data assets.

IQVIA's MEDICAL CLAIMS DATA

Medical claims (Dx) data are pre-adjudicated claims collected from office-based physicians and specialists. These data are sourced from CMS-1500 form-based claim transactions, the standard reimbursement form for all non-cash claims. Medical claims data includes patient-level diagnosis and procedures for visits to U.S. office-based individual professionals, ambulatory and general healthcare sites. The medical claims data includes more than 205 million patients, over 1.7 billion claims and 3 billion service records obtained annually.

IQVIA INSTITUTE DIGITAL HEALTH BILLING CODE DATABASE

The Digital Health Billing Code Database was compiled by the IQVIA Institute to facilitate analyses of medical claims data and contains codes maintained by the AMA and CMS on behalf of various payers to reimburse digital health enabled care. It includes billing codes created for various software-based solutions, mobile devices, digital care programs and services, along with ones that enable the provision of remote patient care or virtual care — e.g., telehealth, telemonitoring and communication technology-based services (CTBS). Approximately 25 custom fields clarify the purpose and use of each supply or service code and billed, including incident-to billing by non-physicians, known products that bill through each, etc.

Methodologies

TIME TO REVENUE FOR DIGITAL THERAPEUTICS

An analysis was conducted of time to revenue for Digital Therapeutics in the CNS Space. These included 27 DiGA listed applications in Germany, nine solutions with NICE full or Early Value Assessment in the United Kingdom, nine solutions on public/private formulary in the United States and three solutions assessed by MHLW in Japan. For the three products assessed in Japan, these were not limited to CNS product but included all solutions approved due to the limited set. The manufacturer's incorporation date was used as a proxy for discovery.

MULTI-COUNTRY REMOTE CARE STUDY

A survey-based study was conducted from April to June 2023 across 11 countries to explore healthcare providers' perspectives on the greatest success factors and challenges facing digital solutions in the coming years. The study included 1,594 providers across General Practice (excluding Japan), Internal Medicine (Japan only), Pediatrics, Neurology, and Psychiatry. A total of 1,594 responses were received regarding remote patient management (with 140–147 responses per country), and 873 responses addressed questions related to digital therapeutics, defined as: "Patient-facing software applications that help patients treat, prevent, or manage a disease." The percentage of healthcare professionals rating each a major success factor or challenge was defined as those rating an element a four or five on a scale of 1–5.

CPT AND HCPCS CODE SETS

According to the American Academy of Professional Coders, HCPCS Level I refers to the Current Procedural Terminology (CPT-4) Category I code set — a numeric system maintained by the American Medical Association (AMA) — used to report procedures and services performed by qualified healthcare professionals for reimbursement. HCPCS Level II is a standardized alphanumeric coding system maintained by the Centers for Medicare & Medicaid Services (CMS), primarily used to identify items and services not included in CPT codes. These include "medical devices, supplies, medications, ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)…. These HCPCS Level II codes were established because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes," reflecting the broader range of benefits reimbursed by Medicare and other insurers."[282]

BILLING CODES NOT SPECIFIC TO VIRTUAL CARE

For billing codes not inherently tied to digital health tools and virtual care — such as telehealth billing or non-face-to-face services like remote monitoring — claims data were adjusted using telehealth modifiers and place-of-service indicators. For codes not specific to telehealth, the charted trends (where noted) reflect telehealth-specific values. In this analysis, a fixed telehealth share per code was calculated from Q1 2025 data and applied across all time periods. As a result, trends for these codes from 2024–2025 represent billing patterns rather than actual shifts in telehealth use over time.

References

1. Digital Health Trends 2024: Implications for Research and Patient Care. IQVIA Institute for Human Data Science, December 2024.
2. Ada. Helping patients navigate their care journey with AI. Accessed Oct 10, 2024. Available from: https://ada.com/improving-care-navigation-at-sutter-with-ai/
3. NICE. Medical Technologies Evaluation Programme. Digitally enabled therapies for adults with depression. Final scope. 2022 Nov. https://www.nice.org.uk/guidance/hte8/chapter/1-Recommendations
4. Vori Health. Vori Health secures $53 million in Series B funding to transform value-based musculoskeletal care. 2025 Mar 11. Available from: https://www.vorihealth.com/resource/vori-health-secures-53-million-in-series-b-funding.
5. Digital Therapeutics Alliance. Exploring Regulatory and Reimbursement Pathways for DTx: United States. Webinar. 2025 Mar 6. Available from https://us02web.zoom.us/rec/play/16RBpu-K5Gpm62kCjMPn2dRaa7YhqSYGOZMh4SnPOBvk1MFlAS8L5ik2Dv9dkDnDCu7N4y137YfbXt7t.pLBH9gpeYclpSKBt?
6. Villeneuve N. Swing Care and Big Health Partner to Bring First-Line Insomnia Treatment to Fibromyalgia Patients. Swing Care Blog. 2025 Feb 6. Available from: https://www.swing.care/blog/swing-care-big-health-insomnia-treatment/
7. Peterson Health Technology Institute. 2024 State of Digital Health Purchasing. 2024 Mar. Available from: https://phti.org/wp-content/uploads/sites/3/2024/10/PHTI-2024-State-of-Digital-Health-Purchasing-Survey.pdf
8. Curio. MamaLift. For Patients. [Accessed Jan 24, 2025]. Available from: https://mymamalift.com/how-it-works-patients/
9. Apple App Store preview. MamaLift. Curio Digital Therapeutics Inc. [Accessed Feb 5, 2025]. Available from: https://apps.apple.com/ca/app/mamalift/id1631494980
10. Curio. Digital-first Solutions for Women's Mental Health Driven by AI. [Accessed Mar 7, 2025]. Available from: https://www.curiodigitaltx.com
11. Curio. Using AI to predict health problems before they're problems.[Accessed Jan 29, 2025]. Available from: https://www.curiodigitaltx.com/curio-i
12. Curio. Introducing MamaLift Plus | Curio Digital Therapeutics. [Accessed Jan 24, 2025]. Available from: https://www.curiodigitaltx.com/introducing-mamalift-plus
13. Curio Digital Therapeutics. Meet MamaLift Plus. MamaLift Plus. [accessed 2025 Mar 13]. Available from: https://www.mymamalift.com/meet-mamalift-plus.
14. Curio Care [in progress]. Accessed 2025 Mar 13. Available from: https://curiocare.curiohealthcare.com/landing/mso/user/registration
15. Businesswire. Curio Digital Therapeutics to Attend AHIP Annual Conference and Host Kiosk. June 07, 2023. [accessed 2025 Mar 13]. Available from: https://www.businesswire.com/news/home/20230607005742/en/Curio-Digital-Therapeutics-to-Attend-AHIP-Annual-Conference-and-Host-Kiosk%C2%A0.
16. Big Health. U.S. FDA Grants Clearance for DaylightRx. PR Newswire. Sep 04, 2024. Available from https://www.prnewswire.com/news-releases/us-fda-grants-clearance-for-daylightrx-302238334.html
17. Medicare changes in 2025. 2025 Jan 31. American Psychological Association. [accessed 2025 Mar 7]. Available from: https://www.apaservices.org/practice/reimbursement/government/2025-medicare-changes
18. Frost & Sullivan. 2024 New product innovator in the global women's health digital therapeutics industry. Best practice awards. Available from: https://www.frost.com/wp-content/uploads/2024/10/Curio-Digital-Therapeutics-Final-Award-Write-up.pdf
19. Welldoc. One platform Connecting individuals, care teams and health organizations. Accessed 2024 Feb. Available from: https://www.welldoc.com/solutions/chronic-care-management-platform/
20. Glooko. Glooko Clinical Research. [Accessed 2024 Feb 6]. Available from: https://glooko.com/clinical-research-products/
21. Webb M. MedTech Insight. Referencing David Benshoof Klein, CEO of Click Therapeutics. The Afterlife Of Pear Therapeutics: Korean DTx Maker Discusses Vision For Salvaged Migraine Assets. 2023 Jun 12.
22. BusinessWire. Otsuka and Click Therapeutics Announce the U.S. Food and Drug Administration (FDA) Clearance of Rejoyn, the First Prescription Digital Therapeutic Authorized for the Adjunctive Treatment of Major Depressive Disorder (MDD) Symptoms. 2024 Apr 1. Available from: https://www.businesswire.com/news/home/20240401758231/en/Otsuka-and-Click-Therapeutics-Announce-the-U.S.-Food-and-Drug-Administration-FDA-Clearance-of-Rejoyn%E2%84%A2-the-First-Prescription-Digital-Therapeutic-Authorized-for-the-Adjunctive-Treatment-of-Major-Depressive-Disorder-MDD-Symptoms

23. Mahalo Health. Rapid Digital Therapeutics (DTx) Development Platform. Accessed 2025 Jan 24. Available from: https://www.mahalo.health/products/digital-therapeutics-development-platform
24. Huma. Huma receives world's first and only multi-condition EU MDR Class IIb regulatory approval for its configurable SaMD disease management platform. 2023 Mar 23. Available from: https://www.huma.com/resources/huma-awarded-eu-classiib-software-as-a-medical-device
25. U.S. Chamber of Commerce. How Noom Tapped Psychology and Technology to Build a $400 Million Weight-Loss App. 2021 Feb 17. Available from: https://www.uschamber.com/co/good-company/the-leap/noom-weight-loss-app-technology
26. NPPES NPI Registry. Kaia Health Inc. Available from: https://npiregistry.cms.hhs.gov/provider-view/1326557901
27. Fierce Healthcare. Headspace, Ginger finalize merger to form $3B mental health company. Landi H. Oct 14, 2021. Available from: https://www.fiercehealthcare.com/tech/headspace-ginger-finalize-3b-merger-to-offer-meditation-mindfulness-and-tele-therapy
28. HMS. What Every Healthcare Provider Should Know About NPI Types. [Accessed Feb 26 2025]. Available from: https://hcmsus.com/blog/npi-type-1-vs-type-2
29. National Plan and Provider Enumeration System (NPPES). Curio Digital Therapeutics, Inc. NPI 1710638887 [Internet]. Washington (DC): Centers for Medicare & Medicaid Services; 2022 Jan 11 [cited 2025 Oct 29]. Available from: https://npiregistry.cms.hhs.gov/
30. PRNewswire. YourCoach Health and Twill Partner to Expand Access to Accredited Live Health Coaches. 2022 Jul 21. Available from: https://www.prnewswire.com/news-releases/yourcoach-health-and-twill-partner-to-expand-access-to-accredited-live-health-coaches-301590682.html
31. Swing Care. Terms of Use and Swing Care and Medical Practices Disclaimer. [Accessed Feb 27 2025]. Available from: https://www.swing.care/terms/ and https://www.swing.care/swing-care-and-medical-practices-disclaimer/ from: https://www.swing.care/terms/ "You represent … you have the legal right and authorization to provide all User Information to Swing Care and Medical Group for use as set forth herein and required by Swing Care and the Medical Group Provider. Swing Care or Medical Group may de-identify your information such that it is no longer considered protected health information or personally identifiable information. Swing Care or Medical Group may disclose, aggregate, sell, or otherwise use such de-identified information to third parties for analytics, research, or other purposes."
32. Big Health. What is SleepioRx, and how will it benefit your employees?. 2022 September 28 DOC-1892 Effective 08/2024 [cited 2025 Feb 27]. Available from:https://www.bighealth.com/blog/what-is-sleepio-and-how-will-it-benefit-your-employees
33. BusinessWire. Axena Health launches telehealth services for women seeking effective first-line incontinence treatment. 2024 July 24. Available from: https://www.businesswire.com/news/home/20240724361721/en/Axena-Health-launches-telehealth-services-for-women-seeking-effective-first-line-incontinence-treatment
34. Relivion. telehealth consultations powered by Belugahealth. Accessed 2024 Feb 5. Available from: https://www.relivion.com/relivion-telehealth/
35. Otsuka Precision Health. How to get Rejoyn. Dec 2024. [Accessed Mar 18 2025]. Available from: https://www.rejoyn.com/how-to-get-rejoyn
36. Digital Health Today. Ep18: Elena Mustatea, CEO Bold Health [Podcast]. 2021 Apr 27. Available from: https://digitalhealthtoday.com/transcripts/elena-mustatea-bold-health/
37. Bold Health. 2021 May 20. Bold health's CBT-based IBS self-management app demonstrates efficacy in clinical trial. Cision PR Newswire. [accessed 2025 Mar 8]. Available from: https://www.prnewswire.com/news-releases/bold-healths-cbt-based-ibs-self-management-app-demonstrates-efficacy-in-clinical-trial-301296311.html.
38. NIH Reporter. Project details. A Randomized Controlled Trial of Deprexis; Evaluation of A Computerized Intervention to Decrease Depression and Restore Functioning in Veterans Project Number 1IK2RX004565-01A2 PI is PEARSON, RAHEL. 2024-2029. Available from: https://reporter.nih.gov/project-details/10864655
39. Endeavor. EndeavorOTC. Accessed Nov 22 2024. Available from: https://www.endeavorotc.com/
40. Nerva Health. Nerva completes Mahana therapeutics acquisition to expand access to digital therapies for IBS [Internet]. May 8, 2025. [cited 2025 Jun 18]. Available from: https://www.nervahealth.com/article/nerva-mahana-acquisition
41. Glooko. EHR Integrations(U.S. customers only). [Accessed Jan 23, 2025] Available from: https://developers.glooko.com/docs/ehrintegrations

42. Glooko. Glooko Adds New Enhancements to Billing Export Feature to Streamline Submitting CPT Codes for Remote Patient Monitoring Reimbursement. 2022 Mar 30. Available from: https://glooko.com/new-glooko-remote-patient-monitoring-cpt-code-reimbursement-feature/
43. Biofourmis. ActiGraph Accelerates Clinical Trial Modernization with Transformational Acquisition of Biofourmis Life Science Business. Jan 7 2025. Available from: https://www.biofourmis.com/news-insights/actigraph-accelerates-clinical-trial-modernization-with-transformational-acquisition-of-biofourmis-life-science-business
44. Dario Health. Dario and Twill Join Forces to Shape the Future of Digital Health. 2024 Feb 21. Available from: https://www.dariohealth.com/articles/dario-twill-future-of-digital-health/
45. Dario Announces Complete Integration of Twill Capabilities Across Full Multi-Condition Platform. Oct 17, 2024. Available from: https://dariohealth.investorroom.com/2024-10-17-Dario-Announces-Complete-Integration-of-Twill-Capabilities-Across-Full-Multi-Condition-Platform
46. BBC. NHS apps to improve access to weight-loss jabs. 2023 Aug 15. Available from: https://www.bbc.com/news/health-66503006
47. Schulz B, Weintraub K. Weight loss startup Noom launches program prescribing new weight loss drugs like Wegovy. USA Today. 2023 May 25. Available from: https://www.usatoday.com/story/money/2023/05/25/noom-offers-weight-loss-drugs-like-wegovy-ozempic/70254029007/
48. Weintraub K. WeightWatchers is adding next-generation weight loss drugs like Wegovy to its program. USA TODAY. 2023 Mar 7. Available from: https://www.usatoday.com/story/news/health/2023/03/07/weightwatchers-sequence-wegovy-obesity-weight-loss-drugs/11415201002/
49. Welldoc. Welldoc Expands Chronic Care Digital Health Platform to Include Weight Management. 2023 Oct 4. Available from: https://www.welldoc.com/news/welldoc-expands-platform-weight-management/
50. NHS Department of Health and Social Care. Fit for the future: 10-year health plan for England [Internet]. London: UK Government; 2025 Jul [cited 2025 Jul 21]. Available from: https://assets.publishing.service.gov.uk/media/68760ad755c4bd0544dcae33/fit-for-the-future-10-year-health-plan-for-england.pdf
51. Sleepup [Internet]. São Paulo (BR): [Accessed 2024 Jun 26, 2025 Mar 3, 2025 Nov 1]. Available from: https://en.sleepup.com.br/
52. Shortlister. Cara Care information. Parent company, Mahana Therapeutics, is insolvent and started the process of liquidating its assets - August 30, 2024. Available from: https://www.myshortlister.com/cara-care/vendor-reviews
53. Nerva Health. Nerva completes Mahana therapeutics acquisition to expand access to digital therapies for IBS [Internet]. May 8, 2025. [cited 2025 Jun 18]. Available from: https://www.nervahealth.com/article/nerva-mahana-acquisition
54. Neuroventis. Our Clinical Practice Solution. Accessed 2025 Mar 3. Available from: https://neuroventis.care/our-solution/
55. Hubin E. Belgian Health data company Cascador Health aims for European leadership with strategic acquisitions in immunology and neurology [Internet]. Cascador Health. 2024 Oct 9 [cited 2025 Mar 3]. Available from: https://cascador.health/belgian-health-data-company-cascador-health-aims-for-european-leadership-with-strategic-acquisitions-in-immunology-and-neurology/
56. Businesswire. Virtual Therapeutics, Akili Interactive Enter Into Definitive Merger Agreement to Establish Leading Digital Health Company. 2024 May 29. Available from: https://www.businesswire.com/news/home/20240529504802/en/Virtual-Therapeutics-Akili-Interactive-Enter-Into-Definitive-Merger-Agreement-to-Establish-Leading-Digital-Health-Company
57. MHealthSpot. XRHealth, Amelia Virtual Care merge to create the largest XR therapeutics platform. 2024 Oct 1. Available from: https://mhealthspot.com/2024/10/xrhealth-amelia-virtual-care-merge-to-create-the-largest-xr-therapeutics-platform/
58. FactViewResearch. XRHealth's Immersive Therapy Platform Earns FDA Breakthrough Status. 2023 Dec 29. Available from: https://www.linkedin.com/pulse/xrhealths-immersive-therapy-platform-earns-fda-breakthrough-snx8f/
59. FemTech Insider. XR Health and Amelia Virtual Care Merge to Form VR Healthtech Platform XR Health. 2023 May 1. Available from: https://femtechinsider.com/xr-health-amelia-virtual-care-merger/
60. XRHealth. XRHealth acquires cognitive training VR company NeuroReality. 2024 Nov 6. Available from: https://www.mobihealthnews.com/news/xrhealth-acquires-cognitive-training-vr-company-neuroreality
61. Businesswire. XRHealth Acquires Immersive, Digital Therapeutics Company RealizedCare, Creating the Largest AI-Driven Therapeutic XR Platform Globally. 2025 Feb 18. Available from: https://www.businesswire.com/news/home/20250218507817/en/XRHealth-Acquires-Immersive-Digital-Therapeutics-Company-RealizedCare-Creating-the-Largest-AI-Driven-Therapeutic-XR-Platform-Globally

62. Hagen J. XRHealth receives patent for closed loop biofeedback in VR, AR [Internet]. MobiHealthNews. 2023 Jun 14 [cited 2025 Mar 4]. Available from: https://www.mobihealthnews.com/news/xrhealth-receives-patent-closed-loop-biofeedback-vr-ar
63. XR Health. What We Treat [Internet]. Accessed 2024 Jan 10. Available from: https://www.xr.health/what-we-treat/
64. Access GUDID. SEARCH RESULTS FOR: ("xr health"). Accessed 2024 Jan. Available from: https://accessgudid.nlm.nih.gov/devices/search?query=xr+health
65. Amwell closes acquisitions of SilverCloud Health and Conversa Health [Internet]. Boston (MA): Amwell; 2021 Aug 9 [cited 2025 Nov 1]. Available from: https://business.amwell.com/about-us/news/press-releases/2021/amwell-closes-acquisitions-of-silvercloud-health-and-conversa-health
66. Amwell. Our solutions for employers [Internet]. Boston (MA): SilverCloud by Amwell; [cited 2025 Nov 1]. Available from: https://silvercloud.amwell.com/our-solutions/employers
67. PursueCareRx. The Forefront of Addiction Treatment. [Accessed March 5 2025]. Available from: https://www.pursuecare.com/pursuecarerx/
68. Eddy N, Vecchione A, Hagen J. Optum reportedly finalizing $470M purchase of virtual behavioral care company AbleTo [Internet]. MobiHealthNews. 2020 Apr 8 [cited 2025 Mar 5]. Available from: https://www.mobihealthnews.com/news/optum-reportedly-finalizing-470m-purchase-virtual-behavioral-care-company-ableto
69. Digital Therapeutics Alliance. DTx Integration and Workflow Report. 2024 Sep. Available from: https://dtxalliance.org/wp-content/uploads/2024/09/September-2024-DTx-Integration-and-Workflow-Report_r5.pdf
70. Alivecor. Solutions for Healthcare Professionals. Accessed Oct 23 2024. Available from: https://alivecor.com/hcp
71. AliveCor. Press release. AliveCor Acquires CardioLabs and Sets the Stage for the Launch of Advanced Ambulatory Monitoring Services," June 2, 2021. Available from https://www.kardia.com/press/press_release/alivecor-acquires-cardiolabs-andsets-the-stage-for-launch-of-advanced-ambulatory-monitoring-services/
72. Stanford Byers Center fo BioDesign. Iterating The Business Model In A Nascent Market: Alivecor. 10/26/2021. Available from: https://biodesign.stanford.edu/content/dam/sm/biodesign/documents/case-studies/AliveCor-Iterating-the-Business-Model-in-a-Nascent-Market-FINAL.pdf
73. Nox Health. Nox Health has acquired Somryst (message). Accessed 2024 Jun 12. Available at: https://www.somryst.com/
74. Nox Health. Nox Health has acquired Somryst (message). Accessed 2024 Jun 12. Available at: https://www.somryst.com/
75. Pharmaceutical Technology. Pear Therapeutics: a lesson for future DTx developers. 2023 Oct 24. Available from: https://www.pharmaceutical-technology.com/analyst-comment/pear-therapeutics-a-lesson-for-future-dtx-developers/
76. PursueCare. Digital therapeutics pioneer Pear's treatments get a second life, a year after bankruptcy. Aguilar M. 2024 Aug. 22. Available from: https://www.pursuecare.com/digital-therapeutics-pioneer-pears-treatments-get-a-second-life-a-year-after-bankruptcy
77. The forefront of addiction treatment [Internet]. PursueCare. 2022 [cited 2025 Mar 3]. Available from: https://www.pursuecare.com/pursuecarerx/
78. Bayer. Bayer acquires HiDoc Technologies and Cara Care app for irritable bowel syndrome. 2024 Dec 11. Available from: https://www.bayer.com/media/en-us/bayer-acquires-hidoc-technologies-and-cara-care-app-for-irritable-bowel-syndrome/.
79. Aguilar M. Eyeing GLP-1 opportunity, Click buys assets of Better Therapeutics. STAT News. *product may also remain standalone. 2024 May 22. Available from: https://www.statnews.com/2024/05/22/click-therapeutics-acquire-better-diabetes-assets-glp1-treatment/
80. Click Therapeutics. Click Therapeutics Accelerates Expansion into Obesity and Cardiometabolic Disease With Acquisition of the Assets of Better Therapeutics, Inc. 2024 May 22. Available from: https://www.clicktherapeutics.com/press/click-therapeutics-accelerates-expansion-into-obesity-and-cardiometabolic/
81. Alex Naoumidis. Co-Founder & CEO at Mindset Health | Nerva/ Likely May 6 2025. Available from: https://www.linkedin.com/posts/alexnaoumidis_nerva-mahana-braingut therapy-activity-7325939850979749888-VbhD/
82. Feel Therapeutics. Precision Digital Therapeutics for Mental Health. Accessed 2024 Mar 25. Available from: https://www.feeltherapeutics.com/dtx-precision-digital-therapeutics-for-mental-health
83. Dynamicare. Coverage Pathways Accessed 2024 Feb 14. Available from: https://www.dynamicarehealth.com/insurance
84. mHealthBelgium. All Applications. [Accessed 2025 Feb 24]. Available from: https://mhealthbelgium.be/apps

85. Gouvernement de la République française. National Portal for eHealth Innovation - G_NIUS. Available from: https://gnius.esante.gouv.fr/en/financing/reimbursement-profiles/reimbursability-remote-monitoring

86. GNIUS Early access to reimbursement for digital devices (PECAN). Accessed 2024 Jun. Available from: https://gnius.esante.gouv.fr/en/financing/reimbursement-profiles/early-access-reimbursement-digital-devices-pecan

87. American Medical Association. 2023 Sep 18. AMA sheds light on commercial payer coverage for digital medicine. American Medical Association. [accessed 2025 Jun 23]. Available from: https://www.ama-assn.org/press-center/ama-press-releases/ama-sheds-light-commercial-payer-coverage-digital-medicine

88. Lindera GmbH. Bureaucratic hurdles in care: Lindera on ZDF Mittagsmagazin [Internet]. Berlin: Lindera; 2025 Oct 28 [cited 2025 Oct 29]. Available from: https://lindera.de/de/blog/buerokratische-huerden-in-der-pflege-lindera-im-zdf-mittagsmagazin

89. DiGA and DiPA, Digital Health Applications, [Online Accessed July 8 2025]. Available from: https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/_node.html

90. BfArM "The fast-track procedure for digital health applications (DiGA) according to § 139e SGB V," 2020 Aug 7. Available from: https://www.bfarm.de/SharedDocs/Downloads/E/N/MedicalDevices/DiGA_Guide.html

91. Digital Medicine Society (DiMe). Germany national companion guide – digital medicine society (DiMe). 2024 Nov 14. [accessed 2025 Apr 8]. https://dimesociety.org/international-digital-health-regulatory-pathways/germany/

92. Bundesministerium für Gesundheit. DiGA Directory. Accessed July 8, 2025. Available from: https://diga.bfarm.de/de/verzeichnis

93. Bundesministerium für Gesundheit. Entwurf eines Gesetzes zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG). Berlin: BMG; 2025 Mar 26. Available from: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/D/Kabinettvorlage_Digital-Gesetz-DigiG.pdf

94. Bundesministerium für Gesundheit. Zweite Verordnung zur Änderung der Digitale Gesundheitsanwendungen-Verordnung (DiGAV-AmendV-E). Berlin: BMG; 2025 Jan. Available from: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/D/2._DiGAV_AendV_RefE.pdf

95. Sante. Assessment principles established by CNEDIMTS. 2019. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2019-11/assessment_principles_established_by_cnedimts.pdf

96. Ameli. l'Assurance Maladie. Liste des Produits et Prestations. LATM - LISTE DES DMN-TSM. Available from: http://www.codage.ext.cnamts.fr/codif/tips//chapitre/index_chap.php?p_ref_menu_code=1718&p_site=MEDIAM

97. Sante. Telemedicine. 2020. Available from: https://sante.gouv.fr/IMG/pdf/rapport-parlement-novembre2020_v5-2.pdf

98. Haute Autorité de Santé. HELLOBETTER Insomnie – Avis de la CNEDiMTS du 23 juillet 2024. Saint-Denis La Plaine: HAS; 2024. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2024-08/hellobetter_insomnie_pecan_6_avis_de_la_cnedimts_du_23_07_2024__occulte.pdf

99. HAS. Transcription des Débats. CONTINUUM + CONNECT Transcription du 25 juin 2024. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2024-07/continuum__connect_transcription.pdf

100. Haute Autorité de Santé. OTO – Avis de la CNEDiMTS du 11 juin 2025 (PECAN). Saint-Denis La Plaine: HAS; 2025 [cited 2025 Nov 3]. Available from: https://www.has-sante.fr/jcms/p_3609400/fr/oto

101. Haute Autorité de Santé. ODYSIGHT – Avis de la CNEDiMTS du 7 octobre 2025 (PECAN). Saint-Denis La Plaine: HAS; 2025 [cited 2025 Nov 3]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2025-10/odysight_pecan-13_avis_de_la_cnedimts_du_07_10_2025.pdf

102. Haute Autorité de Santé. LUDOCARE JOE – Avis de la CNEDiMTS du 17 janvier 2025 (PECAN). Saint-Denis La Plaine: HAS; 2025 [cited 2025 Nov 3]. Available from: https://www.has-sante.fr/jcms/p_3582100/fr/ludocare-joe

103. Intégration de l'impact organisationnel dans les critères d'évaluation de la CNEDiMTS : mise à jour du guide de dépôt des dossiers. Saint-Denis La Plaine: HAS; 2023 [cited 2025 Nov 3]. Available from: https://www.has-sante.fr/jcms/p_3337475/fr/integration-de-l-impact-organisationnel-dans-les-criteres-d-evaluation-de-la-cnedimts-mise-a-jour-du-guide-de-depot-des-dossiers

104. U.S. Census Bureau. Health insurance coverage in the United States: 2023. 2024 [cited 2025 Apr 14]; Available from: https://www.census.gov/library/publications/2024/demo/p60-284.html

105. Kaiser Family Foundation. Health Insurance Coverage of the Total Population [Internet]. KFF; 2023 [cited 2025 Nov 3]. Available from: https://www.kff.org/other/state-indicator/total-population/

106. U.S. Food and Drug Administration. Artificial Intelligence-Enabled Medical Devices [Internet]. Silver Spring (MD): FDA; [cited 2025 Aug 18]. Available from: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices

107. FDA. Guidance Document. Regulatory Considerations for Prescription Drug Use-Related Software. 2023 Sep. Available from: https://www.fda.gov/media/172165/download

108. Fierce Healthcare. Gliadkovskaya A. Floreo nabs FDA breakthrough label for its VR software. 2023 Dec 11. Available from: https://www.fiercehealthcare.com/regulatory/floreo-nabs-fda-breakthrough-label-its-vr-software

109. FDA. Total Product Life Cycle Advisory Program (TAP). 2025 Jul 31. Available from: https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap

110. NHS England. Digitally enabled therapies assessment criteria. Accessed Feb 4 2025. Available from: https://www.england.nhs.uk/mental-health/adults/nhs-talking-therapies/digital/assessment-criteria/

111. NICE. Medical Technologies guidance (including Digital Health Technologies Guidance). Accessed 2023 Jun. Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance

112. NHS England. Building an integrated, rules-based medical technology (medtech) pathway: engagement on proposals [Internet]. NHS England; 2024 [cited 2025 Jul 25]. Available from: https://www.england.nhs.uk/long-read/building-an-integrated-rules-based-medical-technology-medtech-pathway-engagement-on-proposals

113. NICE. LinkedIn Post. 2025 Feb 10. HealthTech manual update. Available from: https://www.linkedin.com/posts/national-institute-for-health-and-care-excellence_healthtech-manual-update-activity-7294647407022100480-fP6B

114. NICE. Early Value Assessment (EVA) for MedTech. Accessed Feb 4, 2025. Available from: https://www.nice.org.uk/about/what-we-do/eva-for-medtech.

115. NICE. Published: Guidance, quality standards and advice. Health technology evaluations (20). [Accessed Apr 2 2025]. Available from https://www.nice.org.uk/guidance/published?ndt=Guidance&ngt=Health%20technology%20evaluations&ps=9999

116. NICE. Early Value Assessment (EVA) for MedTech. Accessed Feb 4, 2025. Available from: https://www.nice.org.uk/about/what-we-do/eva-for-medtech.

117. INAMI. Soins à distance : Télésurveillance et orientation thérapeutique en cas d'insuffisance cardiaque chronique . Available from: https://www.inami.fgov.be/fr/themes/soins-de-sante-cout-et-remboursement/les-prestations-de-sante-que-vous-rembourse-votre-mutualite/telesurveillance-en-cas-d-insuffisance-cardiaque-chronique

118. beMedTech. Seven reimbursed apps for remote monitoring in chronic heart failure. mid-February 2025. Available from: https://bemedtech.be/fr/actualite/nouvelles/sept-apps-rembourses-pour-la-tlsurveillance-en-cas-dinsuffisance-cardiaque-chronique/

119. mHealthBelgium. LinkedIn Post. Vandeput, Steven. mid-February 2025. Available from: https://www.linkedin.com/posts/stevenvandeput_mhealth-heartfailure-telemonitoring-activity-7296187410671910912-iGwQ/

120. mHealthBelgium. Financing. [Accessed 2025 Feb 24]. Available from: https://mhealthbelgium.be/fr/financement

121. IQVIA Institute. Digital Health Trends 2021: Innovation, evidence, regulation, and adoption [Internet]. Durham (NC): IQVIA; 2021 Jul 22 [cited 2025 Jul 16]. Available from:

122. Agoria. Telemonitoring Reimbursement for Heart Failure: A Long-Awaited Breakthrough. 04/12/2024. Available from: https://www.agoria.be/en/services/expertise/digitalisation/healthtech/telemonitoring-reimbursement-for-heart-failure-a-long-awaited-breakthrough

123. Inami. Accessed Jul 1 2025. Centers that have joined the convention/ "Remote care: Telemonitoring and therapeutic guidance in cases of chronic heart failure. Available from: https://www.inami.fgov.be/SiteCollectionDocuments/liste_telesurveillance_insuffusance_cardiaque_lijst_telemonitoring_chronisch_hartfalen.pdf

124. Belgian Working Group on Heart Failure. List of medical centers with certified heart failure cardiologists and nurses. Brussels: BWGHF; [cited 2025 Aug 25]. Available from: https://www.heartfailure.be/en/medical-centers-2/

125. Digizo.nu. Proceszoeker – overzicht van digitale zorgbeoordelingen [Internet]. Digizo.nu; [cited 2025 Aug 18]. Available from: https://digizo.nu/proceszoeker/

126. Digizo.nu. Eindrapportage Behandeling met digitale EMDR in de geestelijke gezondheidszorg . 2025 Jan. https://digizo.nu/wp-content/uploads/2025/02/DIGIZO.NU-Eindrapportage-Behandeling-met-digitale-EMDR-in-de-geestelijke-gezondheidszorg-januari-2025.pdf
127. Digizo.nu. Eindrapportage: Behandeling middels eHealthplatformen in de geestelijke gezondheidszorg. Versie 1.1, januari 2025. [Internet]. Den Haag: Digizo.nu; 2025 [cited 2025 Jul 29]. Available from: https://digizo.nu/wp-content/uploads/2025/02/DIGIZO.NU-Eindrapportage-Behandeling-middels-eHealthplatformen-in-de-geestelijke-gezondheidszorg-januari-2025.pdf
128. Digizo.nu. ZonMw subsidie beschikbaar voor Digizo.nu processen in gerichte ZonMw call [Internet]. Digizo.nu; [cited 2025 Aug 18]. Available from: https://digizo.nu/voor-onderzoekers/
129. Ministry of Food and Drug Safety. Guidelines on review and approval of digital therapeutics [Internet] Cheongju: Ministry of Food and Drug Safety; 2020 Nov 4. Available from: https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72624
130. Digital health in Japan and Korea, where it is heading [Online]. 2022. Available from: https://healthadvancesblog.com/2022/05/04/digital-health-in-japan-and-korea-where-is-it-heading/
131. Manifest. Introducing Korea's Digital Medical Products Act (DMPA) and Manifest Available in Korean. 2025 Feb 5. Available from: https://www.manifestcyber.com/blog/introducing-koreas-digital-medical-products-act-dmpa-and-manifest-available-in-korean
132. ISPOR 2023. Choi D et al. Introduction of an Integrated Review and Assessment System for Artificial Intelligence and Digital Innovative Medical Devices in Korea [poster HPR133]
133. Digital Therapeutics Alliance. Current Status of DTx Reimbursement and Adoption in Korea [Webinar]. 2024 Sep 19
134. Korea Biomedical Review [Online]. 2022 May 26. Available from: https://www.koreabiomed.com/news/articleView.html?idxno=13762
135. Aimmeds Insomnia app approved as Korea's first digital therapeutic [Online]. 2023 Feb 15. Available from: https://pink.pharmaintelligence.informa.com/PS147750/Aimmeds-Insomnia-App-Approved-As-Koreas-First-Digital-Therapeutic.
136. Korea Biomedical Review. Welt, Aimmed face delays in launching Korea's first approved DTx devices. Published 2023 Aug 18. Available from: https://www.koreabiomed.com/news/articleView.html?idxno=21865
137. Won Shin J. Pink Sheet. Aimmed's Insomnia App Approved As Korea's First Digital Therapeutic But Reimbursement Decision May Take Time. 2023 Feb 15. Available from: http://pink.citeline.com/PS147750
138. Digital Therapeutics Alliance. "JP, regulatory and reimbursement pathways," [Online]. 2022 Jan. Available: https://dtxalliance.org/wp-content/uploads/2022/01/Japan-Regulatory-and-Reimbursement-Pathways.pdf
139. "Current Medical Technology Reimbursement System in Japan," [Online]. 2023. Available: https://www.valuehealthregionalissues.com/article/S2212-1099(22)00206-0/fulltext.
140. PMDA. Japanese Regulatory Considerations for Digital Health Technology Pharmaceuticals and Medical Device Agency (PMDA). Viva 2023. Available from: https://www.pmda.go.jp/files/000266816.pdf
141. Digital Medicine Society (DiMe). Japan national companion guide. 2024 Nov 13. [accessed 2025 Mar 18]. Available from: https://dimesociety.org/international-digital-health-regulatory-pathways/japan/.
142. IMDRF. Regulatory Updates on Medical Devices in Japan. Tomoyuki M. 2023 Sep 26. [PowerPoint Presentation]. Available from: https://www.imdrf.org/sites/default/files/2023-10/Japan%20%28MHLW%29%20Update%20-%2024th%20Session.pdf
143. Ministry of Economy, Trade and Industry (Japan). Third Report of the Committee on New Direction of Economic and Industrial Policies. Committee on New Direction of Economic and Industrial Policies, Industrial Structure Council Ministry of Economy, Trade and Industry. June 2024. Available from: https://www.meti.go.jp/english/policy/economy/industrial_council/pdf/240628001_01.pdf
144. Pharmaceuticals and Medical Devices Agency. List of Approved Medical Devices: April 2004 to December 2024. Tokyo: PMDA; [cited 2025 Aug 25]. Available from: https://www.pmda.go.jp/files/000276594.pdf
145. Teijin . CureApp and Teijin Pharma Sign Agreement for Joint Marketing and Sales of Prescription Digital Therapeutic App for Hypertension. 2024 Jun 6. Available from: https://www.teijin.com/news/2024/06/06/20240606_01.pdf
146. Ministry of Health of Brazil. 1st Brazilian National Digital Health Strategy 2020-2028 Monitoring and Evaluation Report. 2021. Available from: https://bvsms.saude.gov.br/bvs/publicacoes/1st_brazilian_national_digital_health_strategy.pdf
147. Brazilian National Digital Health Strategy. 2020. Available from: https://bvsms.saude.gov.br/bvs/publicacoes/strategy_health_digital_brazilian.pdf

148. Kaia Health and United Healthcare. Virtual Physical Therapy for Back & Joints [Internet]. New York: Kaia Health; [cited 2025 Sep 26]. Available from: https://lp.kaiahealth.com/

149. Anthem Blue Cross and Blue Shield. Learn to Live: A Digital Mental Health Benefit for Anthem members! [Internet]. Provider News; 2024 Aug 1 [cited 2025 Aug 18]. Available from: https://providernews.anthem.com/ohio/articles/learn-to-live-a-digital-mental-health-benefit-for-anthem-blu-21037

150. Hinge Health. Is Hinge Health covered by my insurance? [Internet]. Hinge Health Help Center; [cited 2025 Oct 2]. Available from: https://help.hingehealth.com/en/support/solutions/articles/155000002584-is-hinge-health-covered-by-my-insurance-

151. Premera Blue Cross. MEDICAL POLICY – 13.01.500 Prescription Digital Therapeutic. [cited 2025 Apr 18]. Available from: https://www.premera.com/medicalpolicies/13.01.500.pdf

152. OSCAR. Oscar Clinical Guideline: Prescription Digital Therapeutics (PG142, Ver. 1). Accessed 2024 Jun. Available from: https://assets.ctfassets.net/plyq12u1bv8a/4vEt9fymk5WuwAzjiCO29v/c8080904c8a12fe8ebbc459dd2cedc08/PG142_Prescription_Digital_Therapeutics.pdf

153. Molina Clinical Policy. Prescription Digital Therapeutics: Policy No. 412. 2023-2024. Available from: https://www.molinahealthcare.com/~/media/Molina/PublicWebsite/PDF/Common/Molina Clinical Policy/MCP-APR-2022/Prescription-Digital-Therapeutics_R.pdf

154. Cigna.com. Cigna Medical Coverage Policy- Therapy Services. Biofeedback. Effective Date: 11/15/2024 [cited 2025 Apr 18]. Available from: https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/cpg294_biofeedback.pdf

155. Anthem Blue Cross and Blue Shield. Medical Policy: GL.PW.E003562 [Internet]. Indianapolis (IN): Anthem; [cited 2025 Aug 18]. Available from: https://www.anthem.com/medpolicies/abcbs/active/gl_pw_e003562.html

156. Anthem Blue Cross and Blue Shield. Medical Policy: GL.PW.E003555 [Internet]. Indianapolis (IN): Anthem; 2025 Mar 6 [cited 2025 Aug 18]. Available from: https://www.anthem.com/medpolicies/abc/active/gl_pw_e003555.html

157. Highmark. Policy Z-105-008. Prescription Digital Therapeutics. May 5, 2025. Highmark Commercial Medical Policy – Pennsylvania. Available from: https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Miscellaneous/Z-105/Z-105-009.html

158. Highmark. Policy M-86-002. Digital Diagnostics. July 8 2024. Highmark Commercial Medical Policy – Pennsylvania. Available from: https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Diagnostic_Medical/M-86/M-86-002.html

159. Anthem. The Powerful Future Of Virtual Healthcare And Virtual-First Plans [Internet]. Anthem; 2024 Jul 30 [cited 2025 May 5]. Available from: https://www.anthem.com/employer/the-benefits-guide/the-powerful-future-of-virtual-healthcare-and-virtual-first-plans

160. Mercer. Virtual-first health plans, explained [Internet]. Mercer; 2022 Jun 8 [cited 2025 Oct 2]. Available from: https://www.mercer.com/en-us/insights/us-health-news/virtual-first-health-plans-explained/

161. UnitedHealth Group. UnitedHealthcare introduces new rewards program with a modern approach to well-being [Internet]. Minnetonka (MN): UnitedHealth Group; 2023 Feb 8 [cited 2025 Oct 3]. Available from: https://www.unitedhealthgroup.com/newsroom/2023/2023-02-08-uhc-introduces-rewards-program-well-being.html

162. PursueCare. https://www.pursuecare.com/site-map/ Insurance by state. Accessed 20 Sept 2025.

163. Carelon Behavioral Health. Understanding youth mental health in the United States Available from. https://www.carelonbehavioralhealth.com/perspectives/youth-mental-health-crisis Accessed 17 Aug 2025.

164. Aetna Better Health. Aetna Community Care Program: A personalized approach to health care [Internet]. Aetna Medicaid; [cited 2025 Sep 17]. Available from: https://www.aetnabetterhealth.com/impact/community-care-program.html

165. Aetna. Medicare Advantage D-SNP (Dual Eligible Special Needs Plan) [Internet]. Hartford: Aetna; [cited 2025 Sep 26]. Available from: https://www.aetna.com/medicare/compare-plans-enroll/medicare-advantage-dsnp-plans.html

166. Shulkin D. HealthTech, AI in Healthcare, CPT 2026 https://www.linkedin.com/posts/davidshulkin_healthtech-aiinhealthcare-cpt2026-activity-7375147289205506048-9Myd

167. Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs. Federal Register. Published September 19, 2025. Available from: https://www.federalregister.gov/documents/2025/09/19/2025-18236/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare

168. DLA Piper. CMS issues first HCPCS code and Medicare DME benefit category determination for therapeutic Virtual Reality Device [Internet]. 2023 Mar 31 [cited 2025 Feb 26]. Available from: https://www.dlapiper.com/en-us/insights/publications/2023/04/cms-issues-first-hcpcs-code-and-medicare-dme-benefit-category-determination

169. Consumer Technology Association. CTA Draft Comments to CMS PFS 2024 - Revised v3 [cited 2025 Jun 4]. Available from: https://cdn.cta.tech/cta/media/media/pdfs/cta-medicare-2024-pfs-comments-final.pdf

170. Centers for Medicare & Medicaid Services. 42 CFR §414.202. Available from: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-C/section-414.202

171. MDIC/AppliedVR. Case Study. Innovative Reimbursement Strategy for Digital Therapeutics. January 29, 2024. Available from: https://mdic.org/wp-content/uploads/2024/10/AppliedVR-Case-Study_FINAL.pdf

172. CMS establishes reimbursement pathway for virtual reality program https://www.techtarget.com/virtualhealthcare/news/366597139/CMS-Establishes-Reimbursement-Pathway-for-Virtual-Reality-Program

173. NPI Profile. AppliedVR - NPI 1568110260 - Durable Medical Equipment & Medical Supplies in Van Nuys, CA . Available from: https://npiprofile.com/npi/1568110260

174. CMS. Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations Second Biannual (B2), 2022 HCPCS Coding Cycle. Available from: https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-2-2022-non-drug-and-non-biological-items-and-services.pdf

175. Centers for Medicare & Medicaid Services. Behavioral Health Integration Services [Internet]. Baltimore (MD): CMS; 2025 Apr [cited 2025 Oct 10]. Available from: https://www.cms.gov/files/document/mln909432-behavioral-health-integration-services.pdf.

176. CMS. Fact Sheet: Calendar Year (CY) 2025 Medicare Physician Fee Schedule Proposed Rule. 2024 Jul 10. Available from: https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-proposed-rule

177. Centers for Medicare & Medicaid Services. Calendar Year (CY) 2026 Medicare Physician Fee Schedule (PFS) Proposed Rule (CMS-1832-P) [Internet]. 2025 Jul 14 [cited 2025 Aug 13]. Available from: https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2026-medicare-physician-fee-schedule-pfs-proposed-rule-cms-1832-p

178. Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B. Fed Regist. 2025 Jul 16;90(136):50012–50331. Available from: https://www.federalregister.gov/documents/2025/07/16/2025-13271/medicare-and-medicaid-programs-cy-2026-payment-policies-under-the-physician-fee-schedule-and-other

179. U.S. FDA grants clearance for SleepioRx [Internet]. Bighealth.com. [cited 2025 May 12]. Available from: https://www.bighealth.com/news/us-fda-grants-clearance-for-sleepiorx

180. Published contractor price lists as of Jan 1, 2025 for a Colorado and California locality.

181. The Pharma Letter. Depressing update on Orexo's Deprexis deal [Internet].; 2024 Dec 2. [cited 2025 Apr 17]. Available from: https://www.thepharmaletter.com/depressing-update-on-orexos-deprexis-deal

182. U.S. Department of Health & Human Services. Make America Healthy Again [Internet]. Washington (DC): HHS; [cited 2025 Oct 29]. Available from: https://www.hhs.gov/maha/index.html

183. Pappas M, Pinson S. Reshaping Food as Medicine: New insights from federal and state policymakers [Internet]. Nixon Law Group; 2025 Jul 18 [cited 2025 Aug 13]. Available from: https://nixonlawgroup.com/nlg-blog/2025/7/18/reshaping-food-as-medicine-new-insights-from-federal-and-state-policymakers

184. Congressional Budget Office. Cost Estimate for H.R. 8816, American Medical Innovation and Investment Act of 2024. Washington, DC: Congressional Budget Office; 2024. Available from: https://www.cbo.gov/publication/61118

185. New York State Department of Health. New York Evidence Based Benefit Review Advisory Committee. Canvas Dx as a Diagnostic Aid for Autism in Young Children Health Technology Assessment November 2024. [accessed 2025 Apr 18]. Available from: https://www.health.ny.gov/health_care/medicaid/ebbrac/meetings/2024/docs/2024-11-21_canvas_rpt.pdf

186. Federal Register. Medicare Program; Transitional Coverage for Emerging Technologies - A Notice by the Centers for Medicare & Medicaid Services. 2024 Aug 12. Available from: https://www.federalregister.gov/documents/2024/08/12/2024-17603/medicare-program-transitional-coverage-for-emerging-technologies

187. Rawal P, Quinton J, Hughes D, Fowler L. The CMS Innovation Center's strategy to support high-quality primary care [Internet]. Baltimore (MD): Centers for Medicare & Medicaid Services; 2023 Jun 9 [cited 2025 Oct 16]. Available from: https://www.cms.gov/blog/cms-innovation-centers-strategy-support-high-quality-primary-care

188. Omada Health achieves full CDC recognition [Internet]. Omada Health; 2018 [cited 2025 Nov 6]. Available from: https://www.omadahealth.com/resource-center/omada-health-achieves-full-cdc-recognition

189. Centers for Medicare & Medicaid Services. Kidney Care Choices (KCC) Model [Internet]. Baltimore (MD): CMS; [updated 2024 Dec 1; cited 2025 Oct 21]. Available from: https://www.cms.gov/priorities/innovation/innovation-models/kidney-care-choices-kcc-model

190. Advanced Management USA. Navigating the 2030 value-based care transformation: a guide for PCPs https://www.advancedmanagement.org/2024/10/navigating-the-2030-value-based-care-transformation-a-guide-for-pcps/

191. CY 2025 Physician Fee Schedule final rule. Federal Register / Vol. 89, No. 236 / Monday, December 9, 2024. https://www.govinfo.gov/content/pkg/FR-2024-12-09/pdf/2024-25382.pdf

192. Centers for Medicare & Medicaid Services (CMS). Advanced practice providers (APPs) and incident to services [Internet]. Baltimore (MD): CMS; [cited 2025 Oct 6]. Available from: https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/advanced-practice-nonphysician-practitioners/incident-services-supplies

193. CMS. [Accessed Jul 14, 2025] Available from: https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/advanced-practice-nonphysician-practitioners/incident-services-supplies.

194. Noridian Healthcare Solutions. Incident To Services. Noridian Medicare. [Accessed Jul 14, 2025] Available from: https://med.noridianmedicare.com/web/jeb/topics/incident-to-services.

195. Medicaid.gov. Extension of Grace Period Related to the "Four Walls" Requirement under 42 C.F.R. § 440.90 for Indian Health Service and Tribal Facilities. [cited 2025 Apr 17]. Available from: https://www.medicaid.gov/federal-policy-guidance/downloads/cib11421.pdf

196. Final rule revising the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for 2025. 2024 Nov 27. Available from https://www.govinfo.gov/content/pkg/FR-2024-11-27/pdf/2024-25521.pdf

197. Sohail SH. Cognoa launches first state Medicaid program to cover AI-powered autism diagnostic. HIT Consultant. 2024 Sep 26. Available from: https://hitconsultant.net/2024/09/26/cognoa-launches-first-state-medicaid-program-to-cover-ai-powered-autism-diagnostic/

198. Federal Acquisition Regulation (FAR) Part 38; Veterans Affairs Acquisition Regulation (VAAR) 808.4. Delegation to VA; scope of Federal Supply Schedule. Washington (DC): U.S. General Services Administration; U.S. Department of Veterans Affairs; [cited 2025 Oct 28]. Available from: https://www.acquisition.gov/

199. Veterans Administration. VA Immersive | Defining a New Reality in Health Care. Accessed 2025 Oct Available from: https://www.innovation.va.gov/hil/views/immersive/immersive.html

200. U.S. Department of Veterans Affairs. National Acquisition Center (CCST) MedSurg Catalog Search. Available from: https://www.vendorportal.ecms.va.gov/NAC/MedSurg/List

201. Orexo. Interim Report Q4 2023, incl. Full Year Report. 2024 Feb 8. Available from: https://mb.cision.com/Main/694/3924484/2589855.pdf

202. Healthtech. AppliedVR's latest partnership expands covered access to VR therapeutics for veterans, active military. 2023 Apr 24. Available from: https://www.fiercehealthcare.com/health-tech/appliedvrs-latest-partnership-expands-covered-access-vr-therapeutics-veterans-active

203. PR Newswire. Lovell and MedRhythms Partner to Provide Access to InTandem™ for Veterans and Military Personnel with a Walking Impairment Due to a Stroke. 2023 Nov 08. Available from: https://www.prnewswire.com/news-releases/lovell-and-medrhythms-partner-to-provide-access-to-intandem-for-veterans-and-military-personnel-with-a-walking-impairment-due-to-a-stroke-301981056.html

204. PRNewswire Cision. Orexo's digital therapy deprexis® reimbursed under the U.S. Veterans Affairs Federal Supply Schedule. 2022 Jul 13. Available from: https://www.prnewswire.com/news-releases/orexos-digital-therapy-deprexis-reimbursed-under-the-us-veterans-affairs-federal-supply-schedule-301585508.html

205. The Kings Fund. Integrated care systems explained: making sense of systems, places and neighbourhoods. 2022 Aug 19. Available from: https://www.kingsfund.org.uk/insight-and-analysis/long-reads/integrated-care-systems-explained

206. UK Regulatory and Reimbursement Pathways [Online]. 2022. Available from: https://dtxalliance.org/wp-content/uploads/2022/01/UK-Regulatory-and-Reimbursement-Pathways.pdf

207. NIHR. i4i NIHR & OLS Real World Evidence Supporting Information for Applicant. 2024 Jan 12. Available from: https://www.nihr.ac.uk/i4i-nihr-ols-real-world-evidence-supporting-information-applicants

208. NIHR. Funding opportunities for the life sciences industry. Accessed April 7th. Available from: https://www.nihr.ac.uk/support-and-services/industry/explore/funding

209. Miller, C. B., Carl, J. R., Henry, A. L., Baker, L. (2020). A health economic evaluation of Sleepio at a Fortune 500 company. Available from: https://go.www.bighealth.com/report/health-economic-evaluation.

210. Big Health. Changes to Sleepio availability in England. Aug 23, 2024. Available from: https://www.bighealth.co.uk/blog/changes-to-sleepio-availability-in-england

211. Oxford Health NHS. IAPT. Welcome to Sleepio. Available from: https://www.oxfordhealth.nhs.uk/healthyminds/wp-content/uploads/sites/17/2019/10/Sleepio-info-for-clients.pdf

212. Digital treatment for insomnia that's awaiting NHS England funding secures FDA clearance [Internet]. Health Tech World. 2024 Nov 8. [cited 2025 Feb 27]. Available from: https://www.htworld.co.uk/news/digital-health/digital-treatment-for-insomnia-thats-awaiting-nhs-england-funding-secures-fda-clearance/

213. BigHealth. Scotland becomes first country in the world to make digital therapeutics for anxiety and insomnia available nationally. 2024 Jan 23. Available from: https://www.bighealth.com/news/scotland-becomes-first-country-in-the-world-to-make-digital-therapeutics-for-anxiety-and-insomnia-available-nationally/

214. NHS Inform. Scotland. Get help with your mental health. [Accessed Nov 21, 2024]. Available from: https://www.nhsinform.scot/healthy-living/mental-wellbeing/get-help-with-your-mental-health

215. NICE. Medical technology consultation document Sleepio to treat insomnia symptoms. 2021 Nov. Available from: https://www.nice.org.uk/guidance/mtg70/documents/450

216. Cliffe B, Croker A, Denne M, Stallard P. Supported Web-Based Guided Self-Help for Insomnia for Young People Attending Child and Adolescent Mental Health Services: Protocol for a Feasibility Assessment. JMIR Res Protoc. 2018 Dec 13;7(12):e11324

217. Pharmtech.com. 2024 May 4. [accessed 2025 Apr 4]. https://www.pharmtech.com/view/improving-patient-access-through-the-uk-idap-scheme.

218. NHS England. Building an integrated, rules-based medical technology (medtech) pathway: engagement on proposals. [cited 2024 May 22]. Available from: https://www.england.nhs.uk/long-read/building-an-integrated-rules-based-medical-technology-medtech-pathway-engagement-on-proposals/

219. NICE Guidance Consultation. NICE HealthTech programme manual. In development [GID-PMG10010]. Accessed Feb 10 2025. Available from: https://www.nice.org.uk/guidance/indevelopment/gid-pmg10010/consultation/html-content

220. NICE HealthTech programme. [consultation ended on 6 March 2025]. Available from: https://www.nice.org.uk/consultations/2857/1/introduction

221. National Institute for Health and Care Excellence (NICE). Early value assessment: HealthTech guidance assessments [Internet]. Updated 2025 Oct 23. London: NICE; [cited 2025 Nov 12]. Available from: https://www.nice.org.uk/process/pmg48/chapter/early-use-healthtech-guidance-assessments and https://www.nice.org.uk/process/pmg48/chapter/methods-for-guidance-produced-in-the-nice-healthtech-programme#assessment-and-guidance-details

222. Japan Ministry of Health, Labour and Welfare. Revision of drug price calculation standards for FY2024 [Internet]. Tokyo: MHLW; 2024 Apr [cited 2025 Nov 16]. Available from: https://www.mhlw.go.jp/content/12404000/001192127.pdf

223. Japan Ministry of Health, Labour and Welfare. FY2024 drug pricing system revision [Internet]. Tokyo: MHLW; 2024 Apr [cited 2025 Nov 16]. Available from: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000188411_00045.html

224. Japan Ministry of Health, Labour and Welfare. Chuikyo reimbursement listing for medical devices and diagnostics [Internet]. Tokyo: MHLW; 2025 Jul 16 [cited 2025 Nov 16]. Available from: https://www.mhlw.go.jp/content/10808000/001517949.pdf

225. "Current Medical Technology Reimbursement System in Japan," [Online]. 2023. Available: https://www.valuehealthregionalissues.com/article/S2212-1099(22)00206-0/fulltext.

226. MEDI:GATE NEWS Japanese digital therapy device leader CureApp proves effectiveness in clinical and real-world settings. 12/31/2023 [accessed 2025 Mar 18]. https://www.medigatenews.com/news/2388850794.

227. Japan clears CureApps DTx app hypertension [Online]. 2022 May 8. Available: https://www.mobihealthnews.com/news/asia/japan-clears-cureapps-dtx-app-hypertension.

228. Businesswire. CureApp: Digital Therapeutic App for Hypertension Receives Insurance Coverage, Sales of the Service to Medical Institutions Across Japan Launch on September 1 [Online]. Available: https://www.businesswire.com/news/home/20221031005330/en/CureApp-Digital-Therapeutic-App-for-Hypertension-Receives-Insurance-Coverage-Sales-of-the-Service-to-Medical-Institutions-Across-Japan-Launch-on-September-1 (CureApp).

229. Yakuzaishi Online. 「アルコール依存症の治療補助アプリ」の保険適用について [Internet]. Tokyo: Yakuzaishi Online; 2024 [cited 2025 Nov 12]. Available from: https://yakuzaishi-online.com/%E3%80%8C%E3%82%A2%E3%83%AB%E3%82%B3%E3%83%BC%E3%83%AB%E4%BE%9D%E5%AD%98%E7%97%87%E3%81%AE%E6%B2%BB%E7%99%82%E8%A3%9C%E5%8A%A9%E3%82%A2%E3%83%97%E3%83%AA%E3%80%8D%E3%81%AE%E4%BF%9D%E9%99%BA%E9%81%A9/

230. FISCO. Susmed Inc. Company Report [Internet]. Tokyo: FISCO; 2024 Nov 7 [cited 2025 Nov 12]. Available from: https://www.fisco.co.jp/wordpress/wp-content/uploads/FISCO/susmed_20241107_e.pdf

231. Susmed, which gained approval for their Med CBT-I app for insomnia in February 2023, withdrew its reimbursement request in January 2024 citing the revised requirements and low anticipated reimbursement as barriers and is not currently reimbursed under national health insurance.

232. FISCO Ltd. SUSMED Inc. corporate report [Internet]. Tokyo: FISCO; 2025 Nov 6 [cited 2025 Nov 16]. Available from: https://www.fisco.co.jp/wordpress/wp-content/uploads/FISCO/susmed_20251106_e.pdf

233. Republique Francaise. Arrêté du 22 avril 2024 fixant les valeurs prévues au II de l'article R. 162-117 du code de la sécurité sociale de la compensation financière due au titre de la prise en charge anticipée par l'assurance maladie d'un dispositif médical numérique à visée thérapeutique NOR : TSSS2411239A ELI : https://www.legifrance.gouv.fr/eli/arrete/2024/4/22/TSSS2411239A/jo/texte JORF n°0097 du 25 avril 2024 Texte n° 19

234. Ameli.fr. [cited 2025 Apr 22]. Modalités de mise en place et de prise en charge de la télésurveillance. Available from: https://www.ameli.fr/professionnel-de-la-lpplatm/exercice-professionnel/telesurveillance/telesurveillance-prise-en-charge

235. G_NIUS. Remote monitoring reimbursement. Accessed Jun 2 2025. Available from: https://gnius.esante.gouv.fr/en/financing/reimbursement-profiles/remote-monitoring-reimbursement

236. GNIUS. Brand name or generic line registrations: what are the differences?. Accessed 2024 Jun. Available from: https://gnius.esante.gouv.fr/fr/faites-rembourser-votre-solution-de-telesurveillance/inscriptions-en-nom-de-marque-ou-ligne-generique-quelles-differences

237. mHealthBelgium. Financing [Internet]. Brussels: mHealthBelgium; [cited 2025 Oct 26]. Available from: https://mhealthbelgium.be/financing

238. Remecare. Reimbursement for telemonitoring in heart failure from January 1, 2025. December 2, 2024. Available from: https://www.remecare.eu/blog/reimbursement-for-telemonitoring-in-heart-failure-from-january-1-2025

239. GKV-Spitzenverband. Report of the National Association of Statutory Health Insurance Funds / DiGA Report 2024 . Market development of digital health applications. October 1st, 2023 - December 31st, 2024. Available from: https://digitalversorgt.de/wp-content/uploads/2025/03/SVDGV-DiGA-Report24-ENG.pdf

240. Simon Kutcher. Apps on Prescription: How DiGA Manufacturers Can Prepare for Price Negotiations. 2022 May 26. Available from: https://www.simon-kucher.com/en/insights/apps-prescription-how-diga-manufacturers-can-prepare-price-negotiations.

241. Chalmers M, Hughes J, Medi S, Deshpande M. Analysis of Manufacturer and Negotiated Price Differential of Digital Health Applications (DiGAs) in Germany. MT75 [Poster]. ISPOR Europe 2023 [cited 2025 Apr 22]. Available from: https://www.ispor.org/docs/default-source/euro2023/isporeurope23chalmersmt75poster133114-pdf.pdf?sfvrsn=ca20c9d8_0

242. Bundesministerium für Gesundheit. Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG). 2023 Dec 15. Available from: https://www.bundesgesundheitsministerium.de/ministerium/gesetze-und-verordnungen/guv-20-lp/digig.html

243. Der Spitzenverband Digitale Gesundheitsversorgung e.V. (SVDGV). Stellungnahme des Spitzenverband Digitale Gesundheitsversorgung e.V. 2025 Feb. [Machine translated to English by Google Translate] Available from: https://digitalversorgt.de/wp-content/uploads/2025/02/Stellungnahme-DiGAV2025.pdf

244. BFARM. Medical Devices. Digital nursing application (DiPA)? Available from: https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Nursing-Applications/Interesting-facts/_node.html

245. BfArM. DiPA Guide (The Process for Digital Care Applications (DiPA) according to § 78a SGB XI - A Guide for Manufacturers and Users. DiPA-Leitfaden (Stand 11.10.2023, Version 1.2). Available from: https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/dipa_leitfaden.pdf?__blob=publicationFile

246. National Association of Statutory Health Insurance Physicians (KBV). Digital health applications - billing and reimbursement. January 13, 2025. https://www.kbv.de/html/diga.php

247. HIRA. “Revised Guidelines for Temporary Registration of Digital Therapeutic Devices under Health Insurance” (November 28, 2024) Available from: https://www.hira.or.kr/bbs/bbsCDownLoad.do?apndNo=1&apndBrdBltNo=10400&apndBrdTyNo=2&apndBltNo=157

248. Koreabiomed. [BIO KOREA 2025] Experts urge better infra and pricing for digital therapeutics. 2025 May 12. [accessed 2025 May 17]. https://www.koreabiomed.com/news/articleView.html?idxno=27511.

249. Asia Business Daily. Korea’s first digital therapeutics prescription starts [Internet]. Seoul: Asia Business Daily; 2024 Jan 4 [cited 2025 Nov 12]. Available from: https://www.asiae.co.kr/en/article/2024010419104530339

250. Electronic Times Internet. Korea accelerates digital health adoption with IRAS framework. ETNews [Internet]. 2024 Aug 26 [cited 2025 Nov 16]. Available from: https://www.etnews.com/20240826000197

251. Center for Devices, Radiological Health. 2024 Dec 3. Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-enabled device software functions. U.S. Food and Drug Administration. [accessed 2025 Jun 4]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence.

252. Center for Devices, Radiological Health. 2023 Aug 8. Off-the-shelf software use in medical devices. U.S. Food and Drug Administration. [accessed 2025 Jun 4]. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices.

253. Kim Chan-hyuk. Recognizing RWE as clinical data to speed up developing medical devices. Koreabiomed. 2023.06.02. Available from: https://www.koreabiomed.com/news/articleView.html?idxno=21257

254. National Institute for Health and Care Excellence. Sleepio to treat insomnia and insomnia symptoms [Internet]. London: NICE; 2022 [cited 2025 Oct 20]. Available from: https://www.nice.org.uk/guidance/mtg70

255. ClinicalTrials.gov A Randomized, Controlled Study of Two At-Home Self-Guided Virtual Reality Interventions for Adults With Social Anxiety Disorder. (BVR-100-102). ID NCT06037668. Accessed 2023 Jun. Available from: https://clinicaltrials.gov/study/NCT06037668?term=behavr&checkSpell=false&rank=2#study-plan

256. Clinicaltrials.gov. Amped-PD: Amplifying Physical Activity Through Music in Parkinson Disease (Amped-PD). ClinicalTrials.gov ID NCT05421624. 2024 Aug 1. Available from: https://clinicaltrials.gov/study/NCT05421624?term=MedRhythms&rank=3#study-plan

257. Clinicaltrials.gov. EaseVRx-8w+ for the Treatment of Chronic Lower Back Pain (AVR_HEOR). ClinicalTrials.gov ID NCT05263037. 2022 Feb 21. Available from: https://clinicaltrials.gov/study/NCT05263037

258. Lutz et al 2022 Appropriate controls. 2022 Aug 18. Available from: https://pubmed.ncbi.nlm.nih.gov/36060538/

259. HAS. AVIS SUR LES DISPOSITIFS MEDICAUX. DEPREXIS CNEDiMTS. Opinion adopted 2022 Sep 20. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2022-09/deprexis_6833.pdf

260. Durability of DTx and PDTs [Internet]. Psychiatric Times. 2022 Aug 29. [cited 2025 Jun 5]. Available from: https://www.psychiatrictimes.com/view/durability-of-dtx-and-pdts

261. Consumer Technology Association (CTA®). Issue Brief: Reimbursing Health AI and Innovative Technologies. 2024 Sep 9. Available from: https://cdn.cta.tech/cta/media/media/pdfs/cta-health-ai-reimbursement-issue-brieflinkedin.pdf

262. Peterson Health Technology Institute. Virtual Solutions for Depression and Anxiety: Health Technology Assessment. New York: PHTI; 2025 May. Available from: [https://phti.org/wp-content/uploads/sites/3/2025/05/PHTI-Virtual-Solutions-Depression-Anxiety-Assessment-Report.pdf]

263. Peterson Health Technology Institute. Digital Hypertension Management Solutions: Health Technology Assessment. New York: PHTI; 2024 Nov. Available from: [https://phti.org/wp-content/uploads/sites/3/2024/11/PHTI-Digital-Hypertension-Mgmt-Assessment-Report-v1.1.pdf]

264. Peterson Health Technology Institute. Virtual Musculoskeletal Solutions: Health Technology Assessment. New York: PHTI; 2024 Oct. Available from: [https://phti.org/wp-content/uploads/sites/3/2024/10/PHTI-Virtual-MSK-Solutions-Assessment-Report-v1.3.pdf]

265. Peterson Health Technology Institute. Digital Diabetes Management Solutions: Health Technology Assessment. New York: PHTI; 2024 Apr. Available from: [https://phti.org/wp-content/uploads/sites/3/2024/04/PHTI-Digital-Diabetes-Mgmt-Assessment-Report-v1.1.pdf]

266. IQVIA. An investigation into HCPs’ perceptions of the evolving digital landscape– Part 1: Telemedicine, Jan 2024. Available from https://www.iqvia.com/blogs/2024/01/the-remote-healthcare-revolution-part-1. IQVIA; Multi-Country Remote Care Focus Pilot, April–June 2023.

267. The Guardian. Concern as a third of NHS mental health treatments shift online. Taylor R. 2023 Jul 2. Available from: https://www.theguardian.com/society/2023/jul/02/concern-as-a-third-of-nhs-mental-health-treatments-shift-online

268. Bayer AG. Bayer and Samsung collaborate to study sleep disturbances in menopause using wearable technology [Internet]. Leverkusen: Bayer AG; 2024 [cited 2025 Oct 29]. Available from: https://www.bayer.com/en/newsroom/bayer-samsung-menopause-sleep-study

269. From wearables to "Invisibles": We're collaborating to study itch in sleeping children. Sanofi. Accessed August 31, 2022. https://www.sanofi.com/en/magazine/our-science/from-wearables-to-invisibles-were-collaborating-to-study-itch-in-sleeping-children, 2021.

270. BlueRock Therapeutics to incorporate wearable and invisible contactless digital health technologies from Rune Labs and Emerald Innovations in Parkinson's disease clinical trial. https://www.prnewswire.com/news-releases/bluerock-therapeutics-to-incorporate-wearable-and-invisible-contactless-digital-health-technologies-from-rune-labs-and-emerald-innovations-in-parkinsons-disease-clinical-trial-301770876.html.

271. Biogen. Biogen and Happify Health Collaborate to Support Multiple Sclerosis Patients on Digital Platform 2022 June 22. Available from: https://investors.biogen.com/node/25651/pdf

272. Park A. Senators expand probe of Pfizer, Lilly DTC platforms to include telehealth provider partners. FiercePharma [Internet]. 2025 Mar 14 [cited 2025 Oct 14]. Available from: https://www.fiercepharma.com/marketing/senators-expand-probe-pfizer-lilly-dtc-platforms-include-telehealth-provider-partners [fiercepharma.com]

273. Bayer. Bayer Partners with Huma on Bayer Aspirin Heart Risk Assessment Online Educational Tool to Raise Awareness of Heart Health and its Risk Factors. 2023 Feb 1. Available from: https://www.bayer.com/en/us/bayer-partners-with-huma-0

274. Prenosis. Prenosis announces commercial distribution collaboration with Roche for Sepsis ImmunoScore™ [Internet]. 2023 Oct 3 [cited 2025 Oct 14]. Available from: https://prenosis.com/news/prenosis-announces-commercial-distribution-collaboration-with-roche-for-sepsis-immunoscore/

275. Clinicaltrials.gov. EaseVRx-8w+ for the Treatment of Chronic Lower Back Pain (AVR_HEOR). ClinicalTrials.gov ID NCT05263037. 2022 Feb 21. Available from: https://clinicaltrials.gov/study/NCT05263037

276. Pharma Japan. Teijin to Copromote CureApp's Hypertension Therapy App. April 24, 2024. Available from: https://pj.jiho.jp/article/250845

277. K Bio-Heathcare Salon Japan. [LinkedIn Post]. May 2024. Available from: https://www.linkedin.com/posts/kbhsj_todays-hot-pick-cureapp-teams-up-with-activity-7189101009955090432-M05c/

278. Sawai Pharmaceutical Co., Ltd. Notice regarding the transfer of contractual position in the sales license agreement for the alcohol reduction treatment support app. 2025 Mar 6. Available from: https://www.sawai.co.jp/release/detail/000771.html

279. Akili Interactive. Akili and Shionogi announce strategic partnership to develop and commercialize digital therapeutics in key Asian markets [Internet].. 2019 [cited 2025 Feb 27]. Available from: https://www.akiliinteractive.com/news-collection/akili-and-shionogi-announce-strategic-partnership-to-develop-and-commercialize-digital-therapeutics-in-key-asian-markets

280. Biospace. Akili Announces Positive Results from Shionogi's Phase 3 Clinical Trial of Localized Version of Akili's EndeavorRx for Pediatric ADHD Patients in Japan. 2024 Feb 26. Available from:https://www.biospace.com/akili-announces-positive-results-from-shionogi-s-phase-3-clinical-trial-of-localized-version-of-akili-s-endeavorrx-for-pediatric-adhd-patients-in-japan

281. Shionogi. Shionogi obtains domestic manufacturing and marketing approval for the digital therapeutic app "ENDEAVORRIDE" for pediatric attention-deficit/hyperactivity disorder (ADHD) [Internet] [cited 2025 Feb 27]. Available from: https://www.shionogi.com/global/en/news/2025/02/20250218.html

282. Clements A. 2021 Aug 2. Differentiating HCPCS levels I and II code sets. AAPC Knowledge Center. [accessed 2025 Apr 17]. https://www.aapc.com/blog/80561-differentiating-hcpcs-levels-i-and-ii-code-sets/

283. Kim MJ. 디지털 치료제 제도는 갖췄지만, 최대 20배 차이나는 비급여 장벽은? [Digital therapeutics: The system is in place, but the non-reimbursement barrier is up to 20 times higher]. Business Post. 2025 Jun 3. Available from: https://www.businesspost.co.kr/BP?command=article_view&num=397707

284. Mindmaze. MindMaze and Mount Sinai Launch at Home Tele-Neurorehabilitation Program for Stroke Patients. 2020 Sep 30. https://mindmaze.com/mindmaze-and-mount-sinai-launch-at-home-tele-neurorehabilitation-program-for-stroke-patients/

About the authors

MURRAY AITKEN
Executive Director,
IQVIA Institute for
Human Data Science

As head of the IQVIA Institute for Human Data Science, Murray Aitken provides policy setters and decision-makers in the global health sector with evidence, analysis, and insights that contribute to the advancement of Human Data Science to improve human health outcomes. He is tasked with creating and managing a research agenda that leaders in global governments, payers, providers, academia, and the life sciences industry use to accelerate the understanding of global trends in disease patterns, data science, and technology. This research is used to foster innovation critical to evidence-based decision-making and the advancement of human health.

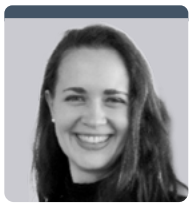
Murray has held various roles throughout his nearly 25-year tenure at IQVIA within healthcare insights, corporate strategy, consulting, and services. Prior to IQVIA, Aitken was a partner at McKinsey & Company in the U.S. and in South Korea, covering a broad range of industries, including life sciences and consumer goods. He holds an MBA, with distinction, from Harvard University and a Master of Commerce from the University of Auckland in New Zealand. In addition to his duties at the IQVIA Institute, Murray is Visiting Professor in Practice, The London School of Economics and Political Science.

DEANNA NASS
Thought Leadership Director,
IQVIA Institute for Human Data Science

As Director of Thought Leadership at the IQVIA Institute for Human Data Science, Deanna develops reports that explore global trends in health technology, patient care, and the life sciences industry. She also creates and analyzes datasets to inform these insights. Deanna joined IQVIA in 2004 and the Institute in 2013 and has held roles spanning consulting, business development, market analysis, and publication. With more than 20 years of industry experience, she brings broad expertise to her research and writing. Deanna holds a B.A. in Biology from Yale University with a specialization in Neurobiology and a Certificate in International Affairs from New York University.

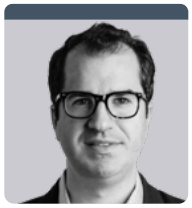
OLIVER BAILEY
Principal,
Integrated Digital Health,
Commercial Strategy Consulting,
IQVIA

Oliver is a Principal in the Integrated Digital Health Center of Excellence, part of IQVIA's strategy consulting team. He leads high-impact projects across digital biomarkers, digital therapeutics (DTx), and broader life science digital health strategy. He provides expert guidance on regulatory and reimbursement pathways, helping to shape evidence generation and commercialization approaches for innovative solutions. He has 10+ years experience leading digital projects for the National Health Service in the UK and holds a Bachelor's in Genetics and Master's in Health Informatics from University College London.



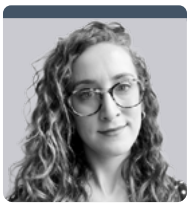
ANNA EXENBERGER, PH.D
Associate Principal,
Integrated Digital Health,
Commercial Strategy Consulting,
IQVIA

Anna is an Associate Principal in the Integrated Digital Health Centre of Excellence embedded in the strategy consulting team, with a strong scientific background and proven track record of driving innovation in healthcare and life sciences. Anna focuses on opportunity identification and evaluation of innovative tools and technologies, such as digital biomarkers or AI-enabled screening tools. Anna holds a Master's degree in Linguistics from Cambridge University, and a Ph.D in Speech Neuroscience from University College London.



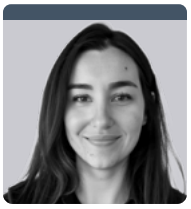
NICK MAGERAS
Principal,
Digital Health COE, Commercial Strategy Consulting,
IQVIA

Nick is a Principal in IQVIA's U.S. Digital Health Strategy Consulting practice, based in San Francisco. He has over 18 years of management consulting and technology strategy experience working with a broad range of healthcare clients. He has expertise in providing digital health and digital transformation advisory solutions to leading global healthcare and life sciences firms. Nick holds a B.S. from the Kelley School of Business at Indiana University.



ERIKA SZEWKIES
Associate Director,
Corporate Alliances,
IQVIA

Erika is an Associate Director in EMEA's Corporate Alliances team, where she oversees relationships between IQVIA and the venture capital ecosystem. Prior to this, Erika spent nine years in IQVIA's Strategy Consulting team, leading commercial strategy engagements with pharmaceutical and biotech companies. During her time in consulting, she worked extensively on commercial strategies for digital health solutions, with a particular focus on reimbursement pathways and evidence planning. Erika holds a Master's degree in Finance from Universidad Torcuato Di Tella in Argentina.



AINHOA URIBARREN
Manager,
Integrated Digital Health,
Commercial Strategy Consulting,
IQVIA

Ainhoa is a Manager in the Integrated Digital Health Center of Excellence, part of IQVIA's strategy consulting team. Ainhoa has supported pharmaceutical, MedTech and digital health companies develop an optimal go-to-market strategy for the past five years. Ainhoa specializes in brining innovation to patient programs, pharmaceutical/MedTech asset launches and the intersection between PMA within drugs and digital health solutions. Her background is in Life Sciences and Biochemical Engineering, with an Honours Programme MSc. from TUDelft, research in oncology at organizations such as Cancer Research UK and University of Cambridge and experience in tech startups.

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry, and payers.

Research agenda

The research agenda for the Institute centers on five areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

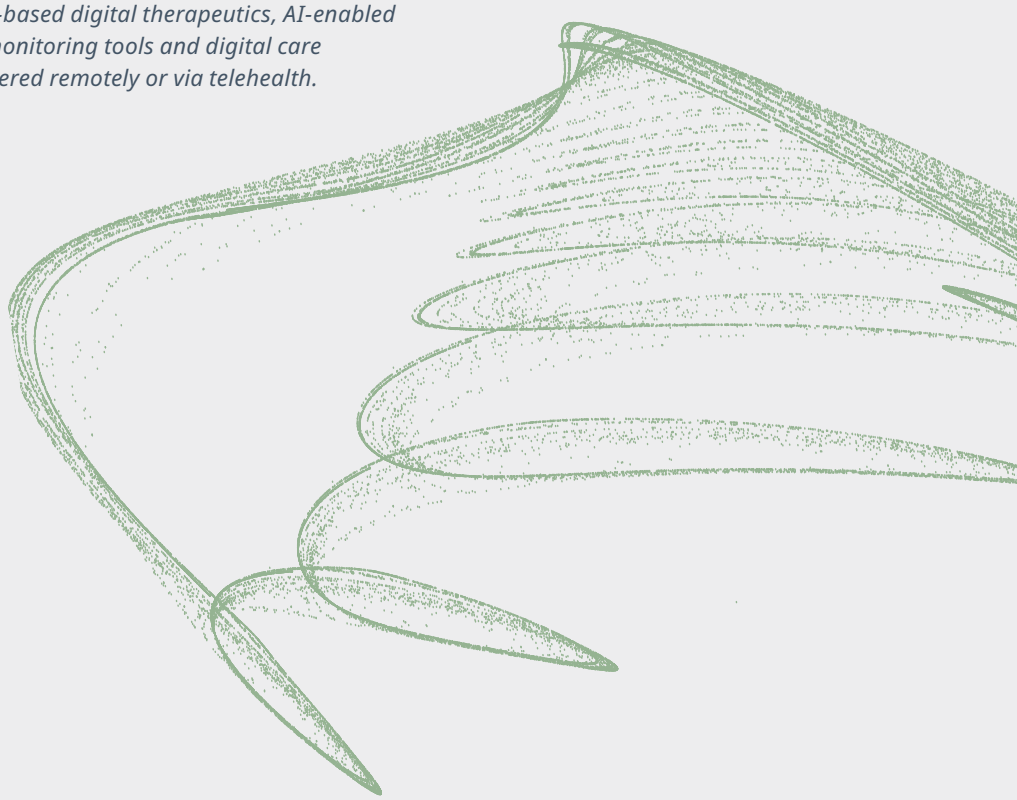
Guiding principles

The Institute operates from a set of guiding principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.

The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.

This algorithmic art is based on the IQVIA Institute Digital Health Billing Code Database, which facilitates analysis of U.S. medical claims and payer reimbursement trends for digital health solutions — including software-based digital therapeutics, AI-enabled tests and diagnostics, sensor-based remote monitoring tools and digital care programs — and related health services delivered remotely or via telehealth.



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CONTACT US
100 IMS Drive
Parsippany, NJ 07054
United States
info@iqviainstitute.org
iqviainstitute.org