DIGITAL THERAPEUTICS TRANSFORMING TREATMENT, MANAGEMENT AND OUTCOMES

Parents are irate when their children seem obsessed with playing video games, but they shouldn't be surprised if the pediatrician prescribes a digital therapeutic treatment for a child with ADHD delivered through an action video game experience.

Written By Laura Carabello

Physician prescriptions for a digital therapeutic may also be on the way for people suffering with abdominal pain associated with Irritable Bowel Syndrome (IBS) --a chronic condition that affects 10-15% of adults in the United States.

Look for the first FDA-authorized Prescription Digital Therapeutic that provides self-administered Gut-Directed Hypnotherapy (GDH) through a convenient iOS and Android app that can be used at home along with other IBS treatments.

Digital Therapeutics (DTx) now emerge as a new category of medicine and the process of obtaining them should look much the same as getting a bottle of pills from the pharmacy. Most providers want to add DTx in combination with other current therapies and use them as a sole intervention or as an alternative to drug therapy.

For those unfamiliar with DTx, the Consumer Technology Association (CTA) recently published a report, "*Assessing the Landscape for Digital Therapeutics*," and proposed this definition which helps clarify this designation for consumers, healthcare providers, payers and industry stakeholders:

Digital therapeutics harness the power of technology to impact health by enhancing traditional medical practices, encouraging behavior change and, in some instances, serving as a direct, stand-alone therapy for a health condition.

Digital therapeutics are validated by clinical evidence to demonstrate an effect on health outcomes for specific treatment pathways, as well as primary and secondary disease prevention.

The DTx Alliance https://dtxalliance.org/, a not-for-profit organization that sets standards and advocates for the industry, advises that DTx deliver medical interventions directly to patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of diseases and disorders.

Broadly defined, DTx products are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes. Incorporating advanced technology best practices relating to design, clinical evaluation, usability, and data security,

DTx are reviewed and cleared or certified by regulatory bodies as required to support product claims regarding risk, efficacy, and intended use. It is suggested that DTx empower patients, clinicians, and payers with intelligent and accessible tools for addressing a wide range of conditions through high-quality, safe, and effective data-driven interventions.

The Alliance recommends that all products claiming to be a digital therapeutic must adhere to these foundational principles:

- Prevent, manage, or treat a medical disorder or disease
- Produce a medical intervention that is driven by software
- Incorporate design, manufacture, and quality best practices
- Engage end users in product development and usability processes
- Incorporate patient privacy and security protections
- Apply product deployment, management, and maintenance best practices

Keep in mind that DTx delivers evidence-based therapeutic interventions via software, like mobile health and wellness apps, that replace or complement the existing treatment of a disease. They diverge from the broader digital health market since they must be approved by regulatory bodies and display proof-of-concept.

CAVEAT EMPTOR

Patient engagement with these apps is a top-of-mind concern for the many companies selling these solutions and the people purchasing them.

According to a new paper published in the Journal *Frontiers in Psychiatry* which scrutinized six clinical trials supporting four mental health apps cleared by the Food and Drug Administration, "there's an urgent need to close the gap between intention and real-world efficacy for digital therapeutics."

Specifically, the authors refer to the shortage of data on how much people use digital treatments and ultimately concluded that some apps may be of fleeting interest to users.

P. Murali Doraiswamy, a professor of psychiatry at Duke University School of Medicine and lead author of the study, said he's elevating the issue as an opportunity to fix the evidence gap but not to deflate the industry.

The authors point out that only a few clinically tested software devices have been authorized by the U.S. Food and Drug Administration for treating specific mental health disorders, excluding devices marketed under pandemic-related emergency use authorization.

These include:

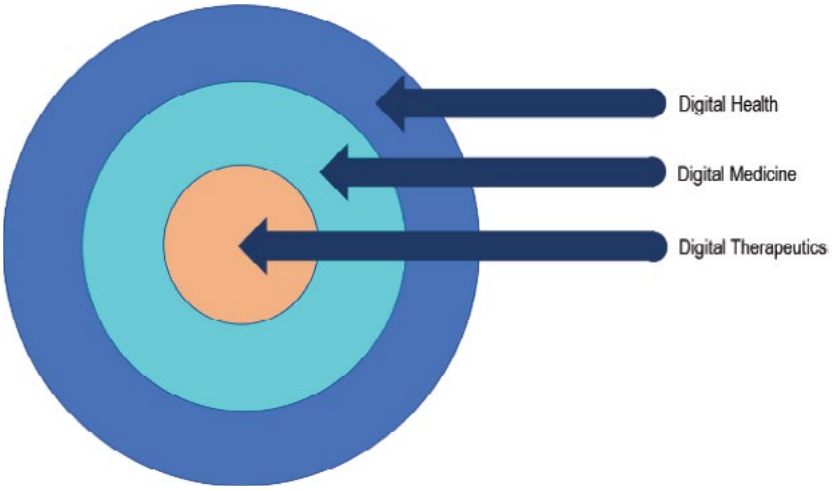
- reSET for substance abuse disorder
- reSET-O for opioid use disorder
- Somryst for chronic insomnia
- EndeavorRx for pediatric attention deficit hyperactivity disorder.
- SaMDs and MMAs for treating mild cognitive impairment, Alzheimer's disease, schizophrenia, autism, depression, social anxiety disorder, phobias, and PTSD are in clinical trials and may also come to market soon.

Another new report published in the *Journal of Medical Internet Research* shows many digital health companies have avoided rigorous clinical evaluation of their products.

Simon C. Mathews, MD, of the Johns Hopkins University School of Medicine and the study's senior and corresponding author advises, "For digital health to be taken seriously and seen as legitimate clinical tools, far more companies need to be engaging in the rigorous processes that are required to show efficacy."

"DIGITAL" CARRIES SEVERAL MEANINGS

The term "Digital" can be paired with many healthcare technology delivery models, so it is important to understand the differences or similarities since not all digital health products are the same. According to the Digital Medicine Society:



Source: https://www.dimesociety.org/about-us/meet-the-team/team-dime/

DIGITAL HEALTH

Digital health is a broad category, including all technologies used for health-related purposes. Examples include online lifestyle platforms and wellness apps, such as step counters or meditation apps. Clinical operations systems also use digital health products and technologies to store or transmit health data. They do not need clinical evidence that they work, and government bodies may not regulate them as medical devices. This is because digital health products have a low risk.

DIGITAL MEDICINE

Digital medicine is one part of digital health and refers to products that measure or intervene in human health or can help monitor and diagnose certain conditions. These products must have clinical evidence that they work, with government groups regulating some of these products as medical devices because digital medicine products have more risk than digital health products.

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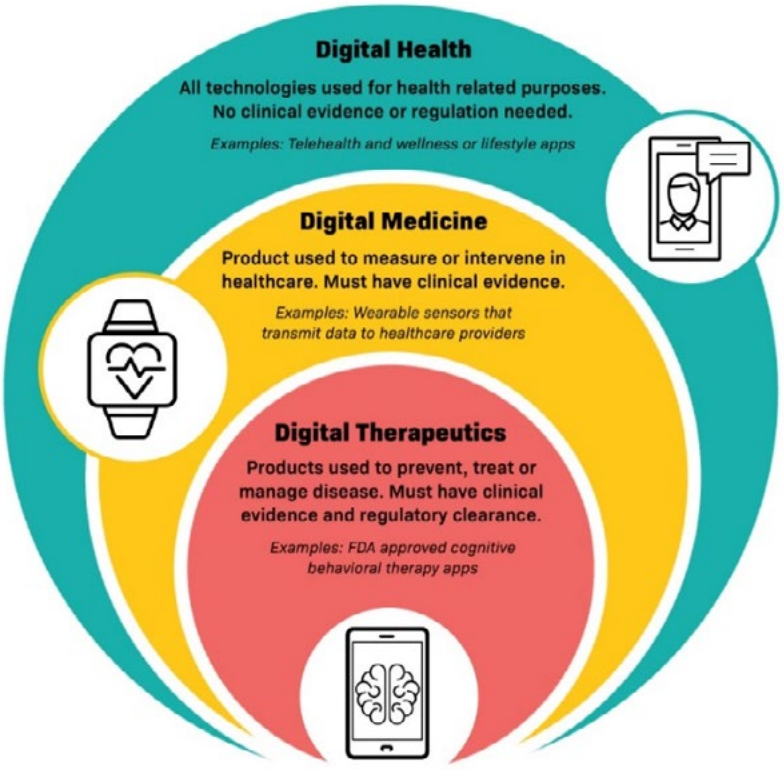
DIGITAL THERAPEUTICS

Digital therapeutics (DTx) is one part of digital medicine, referring to technologies that prevent, manage, or treat a specific disorder or disease. People can use DTx products alone or with other treatments.

DTx products must have clinical evidence of benefits and safety, with government agencies certifying and regulating these products since they pose a higher risk. Regulation helps make sure they work as intended.



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DTX CODING AND REIMBURSEMENT

Establishing a statutory benefit category for prescription DTx took a giant leap forward with the introduction of bipartisan legislation earlier this year: *Access to Prescription Digital Therapeutics Act 2022* would give CMS a path to reimburse for the technology and set out instructions for a payment methodology.

If and when passed, the legislation would establish benefit categories for DTx, and create a coverage and reimbursement framework providing necessary healthcare access for millions of Medicare and Medicaid beneficiaries.

If passed, the Act will establish a payment methodology for manufacturers of prescription digital therapeutics, product-specific HCPCS codes, and a DTx manufacturer reporting process to CMS. It is likely that commercial payers will follow the Medicare/Medicaid lead, making this legislation important for self-funded employers, plan sponsors, and all benefits intermediaries.

This legislation reflects the growing recognition of the clinical and health economic value that DTx products provide to patients, caregivers, and clinicians – particularly with the recognition of increased barriers to care that include social determinants of health that confront patients throughout the United States during and beyond Covid-19.

Stakeholders view this legislation as an important step toward expanded access and appropriate reimbursement for DTx and may be the turning point for marginalized or rural populations to access necessary therapies.

By creating a DTx benefit category and access pathway for treatment, many patients – especially those with chronic and mental conditions – will benefit from remote access to care that can improve outcomes and quality of life.

Expanded coverage for these innovative products will also assist health systems and clinicians to scale their services across broad geographic areas, better manage capacity, drive value and serve communities.

CPT CODING

It is important to remember that CPT codes, the uniform, technical language for healthcare services that serve as the basis for most healthcare billing, do not necessarily guarantee reimbursement—particularly Category III codes intended for "emerging" technologies.

However, a distinct CPT code is often a necessary requirement, establishing legitimacy and credibility in the

healthcare space – especially among payers. The code signifies official recognition that a service is different from what is currently available and merits ongoing review, especially when it comes to collecting targeted data.

What is noteworthy is the American Medical Association CPT Editorial Panel moved last year to establish a new Current Procedural Terminology (CPT) code. It will take effect in January 2023 and apply to remote monitoring of cognitive behavioral therapy. This allows physicians to bill for the time they take to support patients who are leveraging these digital tools.

More recently, CMS established the first Level II Healthcare Common Procedure Coding System (HCPCS) code for prescription digital behavioral therapy.

The code, which became effective April 1, 2022, describes 'Prescription Digital Behavioral Therapy, FDA Cleared, per Course of Treatment,' which includes DTx. The coding decision reflects the growing recognition that DTx products are an important element of care for patients with mental and behavioral health conditions and facilitates options for payers to provide access to these innovative treatments. This also makes it easier for providers to bill private insurers for prescribing the emerging software systems earlier in the treatment trajectory.

A standardized coding mechanism is needed to ensure that payers can cover these interventions under existing reimbursement pathways, providing an important step toward establishing a standard for the coverage and payment of DTx products.

This code facilitates options to reimburse prescription digital behavioral therapies through either pharmacy or medical benefits and eases the way for payers to cover DTX as well as for clinicians to deliver the treatment and patients to access these treatments.

HCPCS Code	Description
A9291	Prescription digital behavioral therapy, FDA cleared, per course of treatment

For conditions like depression, anxiety disorders, opioid and substance use disorders and insomnia, this new designation clears the way to treatment and makes it more affordable for vulnerable and marginalized populations. It also advances initiatives for reimbursement that support wider integration of DTx products into the larger healthcare ecosystem.

HURDLES AHEAD

While getting FDA clearance and CMS coding are important, industry experts identify several challenges to DTx adoption, including getting physician uptake, building more pathways to reimbursement, and most importantly, developing software that patients will want to use.

"There's still a lot of foundational work that needs to be done," says Maya Desai, director of life sciences for Guidehouse, global provider of consulting services. "There's a lot of behavioral change that needs to happen across the stakeholders and their mindsets to think about digital therapeutics as a category of its own."

Differentiating DTC from literally hundreds of thousands of health and wellness apps and other software products also remains a challenge. Every app sponsor is trying to capture the attention of employers and benefits executives and attempting to differentiate their product offerings. The term "prescription" often appends digital therapeutics as a way to distinguish these products.

Many DTx companies are focused on behavioral health, given the enormity of the problems associated with this area and the spotlight on mental health from government and private sectors.

Today, there's also software to help cancer patients manage their symptoms, and virtual reality to treat chronic lower back pain. There's even one for Type 2 diabetes patients who require insulin injection to manage their disease -- the first insulin-management phone app that can titrate personalized doses for all types of insulin regimens and deliver recommendations directly to the patient.

Today, there's a platform for managing respiratory diseases, including Asthma and chronic obstructive pulmonary disease (COPD). It is paired to a smartphone app to automatically track medication use and provide personal insights that help manage and reduce symptoms.

Of course, there's a prescription DTx mobile app intended to help cancer patients manage their symptoms and allow remote progress monitoring.

Most recently, Amerisource Bergen, a leading global healthcare company with a foundation in pharmaceutical distribution and solutions for manufacturers, pharmacies and providers, launched a DTx Platform that will provide a secure connection between developers and physicians by way of the Electronic Medical Record. During a pilot phase that is expected to last six months, just three companies will have products on platform.

A HIGH-GROWTH INDUSTRY

Some industry analysts (Arizton) advise that the U.S. DTx market is expected to reach $8.8 Billion by 2027 with a compound annual growth rate (CAGR) of 33.15% during 2022-2027. Other market researchers (Grandview) state the global DTx market size was valued at USD 4.20 billion in 2021 and is estimated to grow at a CAGR of 26.1% from 2022 to 2030.

The emergence of new DTx products in the U.S. is attributed to constant research and innovation, growth in the prevalence of chronic diseases, increased public awareness, regulatory approvals and an increase in smartphone usage.

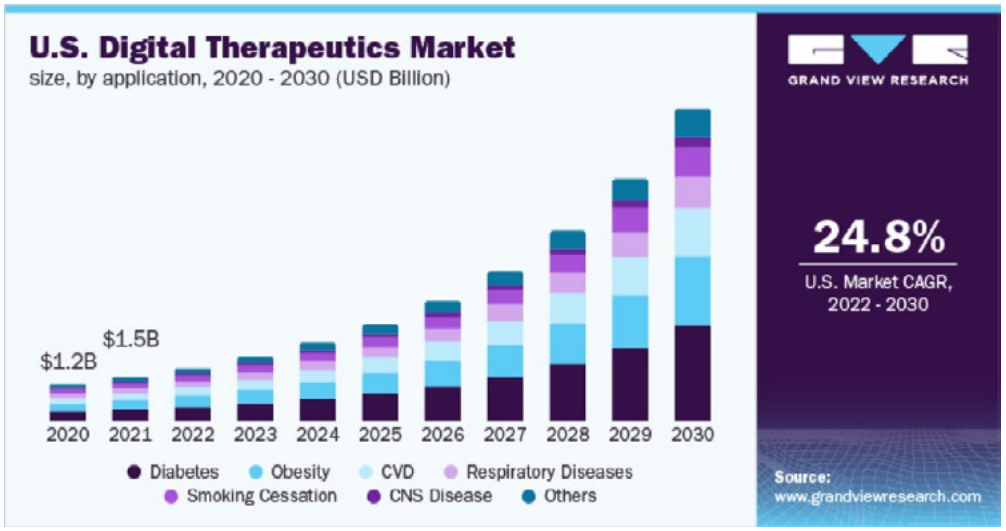
Analysts also cite the rising need to control healthcare costs, growing demand for healthcare applications, the rising importance of Artificial Intelligence, and evolution of digital treatment using virtual reality.

The expanded number of start-ups, strategic acquisitions and collaborations with pharmaceutical companies has contributed to the high availability of funding and investments -- a promising digital therapeutics pipeline. Many telehealth companies are now leveraging digital therapeutics.

As an example, Biogen Inc., an American multinational biotechnology company that considers itself a pioneer in neuroscience, announced a new licensing agreement with the digital therapeutics firm to develop and commercialize an investigational prescription therapy designed to treat gait deficits in patients with multiple sclerosis (MS).

The deal provides a clear commercialization pathway for the digital therapeutics firm, and also bolsters Biogen's footprint in the digital space.

The international pharmaceutical giant Pfizer is teaming up with an Icelandic-based start-up DTx company to launch a new solution for patients with atopic dermatitis (AD). According to Pfizer, the new platform is designed to boost treatment adherence among patients with AD. This is just another partnership in the latest string of DTx investments by Pfizer.



Accompanying this boom are concerns regarding privacy of patient data, technical challenges, high cost, impact of clinical validation, and stringent regulatory guidelines that are expected to limit the growth DTx in the U.S.

However, employers are included on the list of likely end-users, coupled with a favorable trend toward reimbursement for digital medicines. The research states that 25% of organizations are covering them presently and another 45% are planning to do so in the future.

WHAT'S AHEAD FOR EMPLOYERS AND DTX

As payers, self-insured employers will want to see how digital therapeutics affect reimbursement models and overall budgeting. Concurrently, they will be exploring how the patient data collected through such products can be leveraged to inform coverage.

As more self-insured companies incorporate telemedicine, virtual primary care, behavioral telehealth and artificial intelligence (AI)-enabled medical devices into their benefits packages, it is likely that DTx will take a seat in their digital transformation playbook to influence how and when decisions are made about treatment plans and health outcomes. ■

Laura Carabello holds a degree in Journalism from the Newhouse School of Communications at Syracuse University, is a recognized expert in medical travel, and is a widely published writer on healthcare issues. She is a Principal at CPR Strategic Marketing Communications.

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