



# PRESCRIPTION DIGITAL THERAPEUTICS AND MENTAL HEALTH CARE

Exploring the Promise and Evolution of Digital  
Innovation to Improve the Lives of Americans Coping  
with Neuropsychiatric Disorders

## [Executive Summary](#)

The growing mental health crisis in the U.S. coupled with challenges facing health care providers such as workforce and resource shortages calls for an innovative solution. Uniquely poised to address the gaps in care faced by the U.S. health care system (access, equity, provider resources), Prescription Digital Therapeutics (PDTs) are the new frontier in mental health care. PDTs, evidence-based therapies with proven clinical efficacies, offer an opportunity to use technological advancements to shift the landscape of what it means to manage and treat persistent medical conditions.

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## Overview and Introduction

The U.S. health care system confronts persistent cost, quality, and access challenges, in part given the growth in the prevalence of chronic disease, including mental health disorders. Without a commensurate increase in the supply and availability of psychiatric treatment providers, access to treatment for those disorders will remain problematic. However, as the role of technology in health care continues to grow, a new class of therapy is now uniquely positioned to improve those aspects of health care delivery by creating new ways to access care. Advances in information technology, drug therapies, and medical devices offer innovative solutions to the health care system's obstacles through improvements to processes, treatments, and interventions that span a wide variety of diseases and disorders. One such advancement known as prescription digital therapeutics, or PDTs, is defined as evidence-based, clinically evaluated software and devices that can be used as stand-alone therapies or as an adjunctive alongside medications and other therapies to treat physical, behavioral, and mental health conditions.<sup>1,2</sup>

Prescription digital therapeutics bring together advances in technology, biology, and psychology and offer solutions to persistent and chronic mental health conditions with material benefits over previous modes of treatment. PDTs differ from modern general-wellness apps given their clearance and categorization by the FDA as 'software as a medical device' —in addition to requiring a prescription for use by a health care provider. Part of their value is the use of their software's evidence-based approaches that facilitate real-time engagement to ongoing care needs in ways that are consumer-friendly.

In the field of mental health, PDTs offer providers and clinicians a new modality to support, enhance, and improve treatment of a variety of neuropsychiatric disorders where there are currently unmet needs or that are challenging to treat with existing methods and therapeutics.<sup>3</sup> In the case of PDTs, instead of the traditional methods associated with taking a prescription like receiving an injection or swallowing a pill, for example, patients receive their prescribed treatment through digital software. Combined with pharmacological solutions and incorporating validated behavioral therapies, prescription digital therapeutics present new ways to treat mental health disorders with technology that includes

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<sup>1</sup> Vaidya, A. (2023, January 19). *What are Digital Therapeutics and Their Use Cases?* mHealthIntelligence.

<sup>2</sup> Digital Therapeutics Alliance. (2022, September 16). *Understanding DTx*.

<sup>3</sup> Patel, N.A., Butte, A.J. Characteristics and challenges of the clinical pipeline of digital therapeutics. *npj Digit. Med.* **3**, 159 (2020). <https://doi.org/10.1038/s41746-020-00370-8>

patient-centric, software-based tools that treat patients with strategic prompts and psychotherapeutic techniques. The evidence base on the value of PDTs continues to evolve as researchers and publications focus on the promising opportunities of this technology. One such publication concludes that the field of digital therapeutics is here to stay – noting its promise in addressing difficult-to-treat conditions.<sup>4</sup> In particular, PDTs are poised to demonstrate clinical value in both the mental and behavioral health settings. Examples of current use-cases include interactive treatments that support improved focus in those with attention deficit disorders, or sensors which monitor physiological feedback to lessen symptoms related to post-traumatic stress disorder or anxiety.<sup>5</sup> Other examples that could benefit from future PDT clearance relate to treatment of neuropsychiatric disorders such as schizophrenia, a severe and persistent mental illness (SPMI)<sup>6</sup>, that can often cause difficulties related to medication adherence, cognitive function and social behaviors.<sup>7</sup>

For patients, PDTs are familiar, accessible via mobile phones, tablets, or laptop computers, and are pervasive in a wide range of lifestyles and social settings. It is important to note that while their user experience is highly accessible to those using a range of interactive apps, PDTs are not simply “apps” that engage individuals in certain activities; instead, they are innovative therapies considered to be safe and effective as seen in their clearance by the FDA<sup>8</sup> and hold the opportunity to change the landscape for treating persistent health issues. The evolving use of PDTs in the health care system offers the promise to help take on many unmet care needs that currently exist.

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<sup>4</sup> Dang, A., Arora, D., & Rane, P. (2020). Role of digital therapeutics and the changing future of healthcare. *Journal of family medicine and primary care*, 9(5), 2207–2213. [https://doi.org/10.4103/jfmprc.jfmprc\\_105\\_20](https://doi.org/10.4103/jfmprc.jfmprc_105_20)

<sup>5</sup> Brezing, C. A., & Brixner, D. I. (2022). The Rise of Prescription Digital Therapeutics in Behavioral Health. *Advances in therapy*, 39(12), 5301–5306. <https://doi.org/10.1007/s12325-022-02320-0>

<sup>6</sup> Depp CA, Perivoliotis D, Holden J, Dorr J, Granholm EL. Single-Session Mobile-Augmented Intervention in Serious Mental Illness: A Three-Arm Randomized Controlled Trial. *Schizophr Bull*. 2019 Jun 18;45(4):752-762. doi: 10.1093/schbul/sby135. PMID: 30281086; PMCID: PMC6581143.

<sup>7</sup> Wang, C., Lee, C., & Shin, H. (2023). Digital therapeutics from bench to bedside. *NPJ digital medicine*, 6(1), 38. <https://doi.org/10.1038/s41746-023-00777-z>

<sup>8</sup> Patel, N.A., Butte, A.J. Characteristics and challenges of the clinical pipeline of digital therapeutics. *npj Digit. Med.* 3, 159 (2020). <https://doi.org/10.1038/s41746-020-00370-8>



Figure 1. Patient journey with prescription digital therapeutics

## Historical Context

Digital therapeutic (DTx) tools emerged in the late 1990's with the primary goal of reducing the hurdles providers face (time, place, physical or geographical limitations, etc.) when attempting to deliver quality care to all patients.<sup>9</sup> Traditional methods of treating mental and behavioral health disorders were historically limited to medication and/or psychotherapeutic interventions. The emergence of PDTs has broadened the landscape for what is possible in terms of care delivery, treatment, and medication management.

Between 2010 and 2019, researchers in this area conducted more than 500 DTx clinical trials, including about 180 interventional clinical trials. Of these trials, the highest percentage of therapeutic areas under investigation were in fields broadly defined as mental health, including psychiatry, addiction, neurology, and sleep medicine, underscoring the importance and relevance of PDTs in the field of mental health and psychiatry.<sup>10</sup> Today, PDTs deployed in medical practice must meet certain criteria to demonstrate efficacy and meaningful outcomes through multiple levels of clinical evidence.<sup>11</sup>

## Opportunities

<sup>9</sup> Dutta, D. S. S. (2022, April 19). *What are Digital Therapeutics?* News-Medical Life Sciences.

<sup>10</sup> Burrone, V., Graham, L., & Bevan, A. (2022, March 8). *Digital Therapeutics: Past Trends and Future Prospects*. Evidera.

<sup>11</sup> Digital Therapeutics Alliance. (2022, September 16). *Understanding DTx*.

Today, PDTs offer promising opportunities to advance mental health interventions and access, to fill crucial gaps that currently exist in the health care system and to bridge technology with real-time, integrated care. Clearance of additional PDTs may have specific benefits in managing cognitive impairment, substance use, addictions, and SPMIs including schizophrenia, among others.<sup>12,13</sup> Below is a description of benefits to the health system of broader integration of PDTs into clinical practice:

### Access

The future of prescription digital therapeutics presents opportunities to enable broader access to treatment pathways for underserved patients or those with conditions that may prevent them from accessing the level of care they require. 50 million Americans experience mental illness, and over half of all adults coping with these conditions do not receive any treatment or care for their condition.<sup>14</sup>

Accessing affordable mental health services remains a challenge for many given persistent financial barriers and lack of mental health care professionals and services. Despite advancements such as requiring medical insurers to cover mental and behavioral health care via the Affordable Care Act, mental health services can be costly to the patient – especially when dealing with conditions that require frequent visits and treatment programs, such as SPMIs like schizophrenia.

The growing demand for mental health care combined with the lack of psychiatric care providers and services compounds access and bandwidth issues for patients and providers alike. Without an adequate supply of mental health care providers to meet the demand of patients in need, existing providers feel the strain of time and resources. On the other side of the spectrum, patients can experience extended wait times for a visit with a provider and delays receiving care on a consistent, recurring basis.

PDTs allow added engagement and treatment for populations experiencing mental and behavioral disorders who may have been unable to seek this level of integrated care otherwise, especially given technological literacy among growing demographics of Americans.

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<sup>12</sup> Vaidya, A. (2023, January 19). *What are Digital Therapeutics and Their Use Cases?* mHealthIntelligence.

<sup>13</sup> Substance Abuse and Mental Health Services Administration. *Digital Therapeutics for Management and Treatment in Behavioral Health*. Publication No. PEP2306-00-001. Rockville, MD: National Mental Health and Substance Use Policy Laboratory. Substance Abuse and Mental Health Services Administration, 2023.

<sup>14</sup> Mental Health America. (2023). *The State of Mental Health in America*.

## Disparities & Equity

Digital health is an increasingly efficient mode of care delivery that is poised to shrink gaps and disparities in health outcomes by making services broadly available regardless of socio-economic status, geography, or background. Digital health solutions such as PDTs are being developed with an equity lens to reach the populations and underrepresented groups who have historically been more prone to worse health outcomes. PDTs allow for care management and adjustment of the care plan based on real-time feedback – further reinforcing the opportunity to reduce disparities. The advancement and adoption of PDTs contributes to those health equity goals, particularly as interventions that use them can help policymakers tackle the unmet needs of historically underserved and/or rural populations.

## Proactive & Real-Time Care Management

Notably, digital therapeutics facilitate real-time management of chronic conditions. PDTs can shift the landscape of care management for mental and behavioral health disorders to a more proactive approach, allowing patients and providers to anticipate and address problems in real time. This ongoing, managed care allows for solutions to historically challenging issues facing patients and providers dealing with persistent mental health conditions. A common occurrence with patients coping with the burden of SPMIs is medication adherence – an issue that many PDTs are designed to address. Poor medication adherence and monitoring can complicate care pathways and make it more challenging for providers to deliver adequate care in addition to compromising the health of the patient. Opportunities also exist for care providers to glean more accurate and frequent data on medication adherence and related health outcomes.

## Societal Impact

The health care system is increasingly focused on patient-centric care delivery approaches that take into consideration the intersection of mental, physical, behavioral, social, and spiritual health. This “whole person” care integrates resources and technology to promote balance in an individual, and we are seeing more positive health outcomes as a result. New innovations in technology support this approach by leveraging alternative treatment methods for persistent issues that can negatively impact one’s overall health.

Introduction of PDTs into care pathways will undoubtedly have downstream effects for health and wellbeing, but also ultimately society. PDTs seamless integration into daily life may improve the lives of

individuals who struggle with persistent and chronic conditions beyond their health—it may contribute to greater productivity at work and better family relationships.

## State of Innovation & Needs to Move Forward

As prescription digital therapeutics grow in popularity, with greater adoption and use, and as they demonstrate encouraging promise for treating a broad range of diseases and disorders innovators in the sector are increasingly focusing on engagement with government agencies and policymakers to ensure the necessary approvals, appropriate coverage and reimbursement levels, and data and evaluation requirements are in place to move forward.

Because the federal government’s regulatory agency defines prescription digital therapeutics in the same category as medical devices, or ‘software as a medical device’ (SaMD), the FDA ‘clears’ or ‘authorizes’ these tools – ‘approval’ is reserved solely for drugs. Though the terminology differs, the clearance process for SaMDs, and therefore PDTs, also requires evidence of efficacy and safety.<sup>15</sup> Additionally, digital therapeutic products must adhere to core industry principles of quality, safety, and efficacy and maintain privacy standards. As PDTs continue to make their place as an innovative, reliable, and beneficial mental health treatment pathway, there is hope that the path to FDA clearance as a SaMD will be further accepted as a premise for medical necessity, exemplifying equal rigor of evidence as approved drugs. FDA clearance promises an exciting future for PDTs as they can be covered and reimbursed by health plans similar to traditional medication, and treatment centers will begin to use these tools with patients.

Efforts to ensure coverage of PDTs under government programs such as Medicare and Medicaid and private payers continue to evolve at the same time. Similar to other innovative technologies and therapies, ensuring adequate reimbursement for PDTs will be important to encourage their use by providers. As more studies will demonstrate the potential savings from their use and improvements in quality, government programs and private payers may be open to innovative coverage strategies. Further, disparities in reimbursement persist in the U.S. Low reimbursement rates for mental and

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<sup>15</sup> Watson, A., Chapman, R., Shafai, G., & Maricich, Y. A. (2023). FDA regulations and prescription digital therapeutics: Evolving with the technologies they regulate. *Frontiers in digital health*, 5, 1086219. <https://doi.org/10.3389/fdgth.2023.1086219>



behavioral health coupled with in- versus out-of-network barriers compound access challenges for those who need care the most. Of note, PDTs are not currently required or included in Explanation of Benefit (EOB) documents, plan sponsor agreements, or scope of coverage with DOIs in the United States. Support for reimbursement—including development of new codes—can add momentum for the expanding use of PDTs. Including innovators in policymaking in this area – and in mental health broadly – will help to advance the benefits of this new technology.

### Data Exchange and Analytics

Coverage and regulatory hurdles are not the only factors influencing broad adoption of PDTs; technology, data and provider adoption will all continue to be important forces shaping their use.

Improvements in these emerging technologies and their capabilities rely heavily on the rapid exchange of data that safely and securely captures patient outcomes as well as the real-time experiences of providers and plans who are working with them. Improvements in data science and predictive analytics will help spur ongoing innovation in this burgeoning new category of medicine. With improved data references that define the positive health outcomes for patients and reduction of burden on providers, the future of PDTs promises greater provider uptake and increased patient use.

## Outlook

The growing mental health crisis calls out for innovative solutions as the landscape continues to trend towards personalized, accessible, and holistic treatments. PDTs are a key part of the answer and are shifting the paradigm of mental health care and psychiatry. In 2023 alone, there are 154 PDTs with U.S. market intentions – 19 of which have the potential to launch within the next few years.<sup>16</sup> The burgeoning PDT market indicates and underscores their effectiveness as a solution to a wide range of mental health disorders. In addition to supporting approval and reimbursement policies, policymakers can advance solutions that improve coverage of PDTs with incentives for access, including policies that allow for use of certain therapies in non-traditional settings. As we chart a path forward within the new landscape of mental health therapy, we will look to PDTs to address gaps in care by reaching a broad

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<sup>16</sup> Liesch, J., Volgina, D., Nessim, C., Murphy, D., & Samson, C. (2023, March 22). *Prescription Digital Therapeutics U.S. Market Landscape for 2023: Current status of PDT commercialization and upcoming launches*. Blue Matter Consulting.

population (while addressing existing disparities) and introducing real-time feedback to allow care management for those who need it most.