



# 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.

## Overview and Introduction

The U.S. health care system continues to address persistent cost, quality and access challenges, the growth in the prevalence of chronic disease, and rising rates of mental health disorders coupled with a critical undersupply of psychiatric treatment providers. As the role of technology in health care continues to grow, a new class of therapy is now uniquely positioned to address some of our most challenging care pathways. Advances in information technology, drug therapies and medical devices—*prescription digital therapeutics (PDTs)*—offer innovative solutions to those obstacles through improvements to processes, treatments, and interventions that span a wide variety of diseases and disorders. PDTs are defined as evidence-based, clinically evaluated software and devices that can be used as stand-alone therapies or as an adjunctive alongside medications, devices, and other therapies to treat physical, behavioral, and mental health conditions.<sup>1,2</sup>

PDTs are poised to address some of the most challenging issues facing the health care system at the convergence of technology, care pathways, and the burden of persistent conditions. Part of their value is in the software’s digital application-based approaches that facilitate real-time engagement to ongoing care needs in ways that are consumer-friendly. PDTs, Food and Drug Administration (FDA)-cleared interventions, differ from modern general-wellness apps given their categorization by the FDA as ‘software as a medical device’ in addition to requiring a prescription for use by a health care provider. Despite this, PDTs maintain familiarity and ease of use to the consumer or patient through their accessibility via a mobile phone, tablet, laptop computer, etc. Their evolving use in the health care system holds promise to help society take on many unmet care needs that currently exist.

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

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

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

<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>

digital therapeutics present new ways to treat mental health disorders with software that includes consumer facing, software-based tools that help patients with prompts and self-care strategies. Many possible use cases demonstrate the clinical value of PDTs in the mental and behavioral health setting. Examples could 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>4</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>5</sup>, that can often cause difficulties related to medication adherence, cognitive function and social behaviors.<sup>6</sup> It is important to note that while their user experience is familiar and accessible to those using a range of interactive apps, PDTs are not simply “gamified” apps that engage individuals in certain activities; instead, they are innovative therapies that will change the landscape for treating persistent health issues.

### **Historical Context**

Digital therapeutic (DTx) tools emerged in the late 1990’s with the primary goal of alleviating the hurdles providers face (time, place, physical or geographical limitations, etc.) when attempting to deliver quality care to all patients.<sup>7</sup> Traditional methods of treating mental and behavioral health disorders were historically limited to medication and/or psychotherapeutic interventions, but with the addition of PDTs, the landscape for what is possible in terms of care delivery, treatment, and medication management, broadened.

Since that time, researchers in this area conducted more than 500 DTx clinical trials conducted between January 2010 and December 2019, including about 180 interventional clinical trials. Of these trials, the highest percentage of therapeutic areas being investigated were in fields broadly defined as mental

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<sup>4</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>5</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>6</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>7</sup> Dutta, D. S. S. (2022, April 19). *What are Digital Therapeutics?* News-Medical Life Sciences.

health, including psychiatry, addiction, neurology, and sleep medicine <sup>8</sup>, underscoring the importance and relevance of PDTs in the field of mental health and psychiatry. Today, PDTs deployed in medical practice must meet certain criteria to demonstrate efficacy and meaningful outcomes through multiple levels of clinical evidence. <sup>9</sup>

### **Opportunities**

PDTs offer opportunities to advance mental health interventions and access, filling crucial gaps that currently exist in the health care system and bridging 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>10,11</sup>

Access to health care is among the most persistent challenges faced by providers and patients alike. 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. Additionally, given technological literacy among younger generations, PDTs may allow added engagement and treatment for younger populations experiencing mental and behavioral disorders.

Addressing disparities in health outcomes remains a critically important component in favor of the advancement and adoption of digital therapeutics. PDTs hold the promise of reducing gaps in care for patients who are restricted by access, geography, economic status, and language. Tackling the unmet needs of historically underserved and/or rural populations is a key consideration for policymakers when considering the value of these interventions.

Notably, digital therapeutics facilitate management of chronic conditions based on real-time feedback. In the future, PDTs may shift the landscape of care management for mental and behavioral health

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

<sup>9</sup> *Understanding DTx*. Digital Therapeutics Alliance. (2022, September 16).

<sup>10</sup> Vaidya, A. (2023, January 19). *What are Digital Therapeutics and Their Use Cases?* mHealthIntelligence.

<sup>11</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.

disorders to a more proactive approach, allowing patients and providers to anticipate and address problems in real time.

### **Challenges**

While prescription digital therapeutics grow in adoption and use and demonstrate encouraging promise for treating a broad range of diseases and disorders, challenges remain for innovators in the sector regarding approvals, coverage, and data evaluation. The popularity of PDTs is growing among providers and payers and efforts to ensure coverage under government programs such as Medicare and Medicaid continue to evolve. 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.

Despite the challenges with regulatory hurdles, pursuit of an unregulated approach can undermine provider and payer coordination. Coverage and regulatory hurdles are not the only challenge to broad adoption of PDTs; technology, data and provider adoption will all continue to be important forces shaping their use. Improvement in these emerging technologies and their capabilities relies 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.

### **Outlook & Conclusion**

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