

# POLICY BRIEF

## *REALIZING THE PROMISE OF DIGITAL THERAPEUTICS IN MENTAL HEALTH AND SUBSTANCE USE*

Technology has changed almost every aspect of our lives, but mental health and substance use treatment has remained largely unaffected. In some cases, this may be for the best – disruption without evidence may not improve outcomes and may even prove detrimental. There is, however, a clear need for innovation in mental health and substance use treatment. Deaths from suicide and overdose continue to climb, and the incredible need of Americans cannot be met by the status quo. There are not, nor will there be, enough providers to deliver the amount of high-quality mental health and substance use care needed. Other solutions are needed, and evidence-based technology can be a critical source of innovation.

In the past few years, several technologies have undergone rigorous clinical evaluations and demonstrated effectiveness in treating mental health and substance use conditions by extending or enhancing our current care models. A consumer now has the ability to download a clinical-grade app on her phone or computer and rely on it as an integral and engaging mode of treatment for ADHD, depression, insomnia, or even opioid use disorder. These technologies – referred to as digital therapeutics (DTx) – have the potential to fill gaps and increase access to mental health care but are not well addressed by current policy. If health care policy cannot ultimately accommodate these new DTx products, part of the promise of technology for mental health and substance use care may be lost.

To examine this emerging issue, Mental Health America (MHA), the Digital Therapeutics Alliance (DTA), and BrainFutures hosted a Policy Institute to discuss the opportunities and obstacles of DTx product adoption with industry members, clinicians, payers, and patients/consumers. This policy brief synthesizes those findings and examines the field of DTx products, barriers to the effective deployment of DTx products, and policy recommendations that would promote access for individuals who would most benefit from these novel solutions.

## **DIGITAL THERAPEUTICS**

DTA, the leading trade association for DTx companies, defines digital therapeutics in this way:

Digital therapeutics (DTx) deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

DTx products incorporate advanced technology best practices relating to design, clinical validation, usability, and data security. Some DTx products require approval by regulatory bodies to support product claims regarding risk, efficacy, and intended use.<sup>1</sup> Other DTx products do not need to be reviewed or approved by the Food and Drug Administration (FDA) because they do not fall within its enforcement authority.

Among the many potential uses of technology in mental health and substance use, DTx products are unique in that software is an intervention in and of itself.

Outside of DTx, other digital health applications can provide support to providers in care planning, offer population health analytics to administrators, or empower individuals to better understand their own mental health. While all areas of digital health can be important to the future of mental health and substance use, this policy brief focuses specifically on the unique issues facing DTx products.

Because of the high unmet need for effective treatment and access to services, mental health and substance use have been prominent areas of focus for DTx development. Examples of DTx product applications in use or underway in mental health and substance use include:

- Platforms that deliver cognitive-behavioral therapy for depression, anxiety, sleep, and addiction;
- Games that offer sensory and motor stimuli to address cognition in ADHD and depression;
- Cognitive-emotional tasks for improving outcomes for depression; and
- Apps that support parents to address child sleep, ADHD, and anxiety.

Before these products are brought to market, most are supported by research published in peer-reviewed journals. Highlights from some of those studies include:

- Twenty percent more individuals achieved healthy sleep with a DTx than treatment as usual (TAU)<sup>2</sup>
- Individuals were 60 percent more likely to abstain for substance use with a DTx than TAU<sup>3</sup>
- Twenty percent more individuals achieved clinical response for depression with a DTx than TAU<sup>4</sup>
- Better ADHD outcomes for children that discontinue stimulant medications<sup>5</sup>
- Fifty-four percent of individuals experiencing remission of panic disorder within 12 months<sup>6</sup>
- Clinical response in 69.7 percent of individuals with chronic insomnia - 56.6 percent achieving remission<sup>7</sup>

DTx as a field is growing rapidly: new digital interventions for mental health and substance use are already in the pipeline and more will be pioneered in the coming years.

## **BARRIERS TO DEPLOYMENT**

Despite the promise that DTx hold, there are substantial barriers to effective deployment. Unlike pharmaceuticals, which generally have a robust system for integration into care and ensuring access for consumers, DTx products are paid for and integrated into care through a variety of ad hoc approaches (with mixed results).<sup>8</sup> Three of the biggest barriers facing DTx adoption are: 1) poor fit with existing payment mechanisms, 2) lack of support from payers, and 3) lack of provider training on effective use. Each of these is further explored below.

1. *Poor fit with existing payment mechanisms.* Traditional fee-for-service health care reimbursement is organized around the use of CPT codes for compensating for provider time and effort, facility overhead, and malpractice insurance, as well as paying for pharmaceuticals, devices, and durable medical equipment (DME). DTx products do not fit neatly into any of these categories. They are not a traditional pharmaceutical like antidepressant drugs, nor a device like an MRI, nor a piece of durable medical equipment like an insulin pump. They also may take very little provider time and effort and incur no additional facility overhead. Even where existing provider CPT codes cover the kinds of activities needed to support the effective use of DTx products, the descriptions of the CPT codes may inadvertently exclude billing for DTx-related care. Faced with this dilemma, DTx companies and private payers have negotiated some ad hoc payment arrangements, but there is no consistent path for integration of DTx products into health care reimbursement. The reimbursement route can also come with different considerations – for example, if DTx are reimbursed as a pharmaceutical, psychologists and social workers may not be able to prescribe DTx. Without a systematic pathway for integrating DTx products into payment, access to effective DTx products remains uncertain.
2. *Lack of support from payers.* Public payers – Medicare and Medicaid – cover individuals with the greatest need, and often the fewest resources, for accessing care. Fee-for-service Medicare and Medicaid do not currently offer any support for DTx products. If DTx products become a critical part of the nation’s strategy for addressing gaps in access, those who could potentially most benefit would have the least access. Further, clear opportunities for coverage from public payers would promote stronger incentives for ensuring that DTx products meet the needs of a greater diversity of individuals. If reimbursement channels are most flexible in the commercial marketplace, DTx developers will be more likely to design for perceived users in that market, rather than those covered by public payers (and uptake in the commercial marketplace would also be advanced by better mainstreaming into traditional reimbursement pathways).
3. *Lack of provider training on effective use.* Providers are not well equipped to prescribe or support the use of DTx products when appropriate. Most providers were trained before this type of technological innovation was possible. While the process of prescribing a DTx product will eventually be similar to that of traditional therapies once they are incorporated into EHR systems, clinicians will need to understand how DTx products work and how they fit into clinical practice in order to engage and support patients in their use. Meaningful provider education will be necessary to effectively integrate DTx into care delivery.

## **POLICY RECOMMENDATIONS**

Federal leadership can address these barriers to effective deployment of DTx products and ensure that Americans gain access to the best available technologies to support their mental health. The federal government can incorporate DTx products into existing payment mechanisms; provide guidelines for coverage by public payers; and build DTx training into quality improvement initiatives.

Incorporate DTx into existing payment mechanisms:

- The Centers for Medicare & Medicaid Services (CMS) should clearly articulate where DTx products fit within the benefit structure for Medicare, Medicare Advantage (MA), Medicaid, Medicaid Managed Care Organizations (MCOs), and CHIP - or create a new benefit category for DTx products.
- CMS and the Department of Labor (DoL) should clearly articulate where DTx products fit within the regulations for commercial market health insurance plans.

Provide guidelines for coverage by public payers:

- CMS should issue guidance on considerations for covering DTx products under Medicare, and guidance for states in covering DTx products under Medicaid.
- CMS should issue guidance on how coverage and effective deployment of DTx products under Medicaid, Medicaid MCOs, and MA interact with network adequacy and other requirements.
- CMS should revise current Healthcare Common Procedure Coding System (HCPCS) to ensure that they appropriately cover provider time for supporting the use of DTx products in clinical practice.
- The Center for Medicare and Medicaid Innovation (CMMI) should include DTx products in the models they test to determine the most effective ways to integrate these tools into care to produce better outcomes and reduce costs.

Build DTx product training into quality improvement initiatives:

- CMS should include adoption and effective deployment of DTx products as a quality improvement activity in the Quality Payment Program and build this into the foci of quality improvement organizations and related programs.
- The Agency for Healthcare Research and Quality (AHRQ) and the Health Resources and Services Administration (HRSA) should include support for effectively integrating DTx products into practice in their training and technical assistance programs.

---

<sup>1</sup> Digital Therapeutics Alliance. Digital Therapeutics: Combining Technology and Evidence-based Medicine to Transform Personalized Patient Care. Oct 2018. [https://www.dtxalliance.org/wp-content/uploads/2018/09/DTA-Report\\_DTx-Industry-Foundations.pdf](https://www.dtxalliance.org/wp-content/uploads/2018/09/DTA-Report_DTx-Industry-Foundations.pdf)

<sup>2</sup> Espie CA, Kyle SD, Williams C, Ong JC, Douglas NJ, Hames P, Brown JS. A randomized, placebo-controlled trial of online cognitive behavioral therapy for chronic insomnia disorder delivered via an automated media-rich web application. *Sleep*. 2012 Jun 1;35(6):769-81.

<sup>3</sup> Campbell AN, Nunes EV, Matthews AG, Stitzer M, Miele GM, Polsky D, Turrigiano E, Walters S, McClure EA, Kyle TL, Wahle A. Internet-delivered treatment for substance abuse: a multisite randomized controlled trial. *American Journal of Psychiatry*. 2014 Jun;171(6):683-90.

<sup>4</sup> Iacoviello BM, Murrough JW, Hoch MM, Huryk KM, Collins KA, Cutter GR, Iosifescu DV, Charney DS. A randomized, controlled pilot trial of the Emotional Faces Memory Task: a digital therapeutic for depression. *NPJ digital medicine*. 2018 Jun 6;1(1):21.

<sup>5</sup> Kollins SH, Bower J, Findling RL, Keefe R, Epstein J, Cutler AJ, White R, Aberle L, DeLoss D, Faraone SV. 2.40 A Multicenter, Randomized, Active-Control Registration Trial of Software Treatment for Actively Reducing Severity of ADHD (Stars-Adhd) to Assess the Efficacy and Safety of a Novel, Home-Based, Digital Treatment for Pediatric ADHD. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2018 Oct 1;57(10):S172.

<sup>6</sup> Tolin D, McGrath P, et al, A Multisite Benchmarking Trial of Capnometry Guided Respiratory Intervention for Panic Disorder in Naturalistic Treatment Settings, *Journal Applied Psychophysiology and Biofeedback*, 2017, 42: 51-58.

<sup>7</sup> Ritterband LM, Thorndike FP, Ingersoll KS, et al. Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: A randomized clinical trial. *JAMA Psychiatry*. 2017.

<sup>8</sup> Powell AC, Bowman MB, Harbin HT. Reimbursement of Apps for Mental Health: Current Practices and Potential Pathways. *JMIR Mental Health*. 2019 Aug 6;6(8).

## PARTNERS



Mental Health America (MHA) - founded in 1909 - is the nation's leading community-based nonprofit dedicated to addressing the needs of those living with mental illness and promoting the overall mental health of all Americans. Our work is driven by our commitment to promote mental health as a critical part of overall wellness, including prevention services for all; early identification and intervention for those at risk; integrated care, services, and supports for those who need it; with recovery as the goal.

## DIGITAL THERAPEUTICS ALLIANCE



The Digital Therapeutics Alliance (DTA) is a global non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. DTA exists to broaden the understanding, adoption, and integration of clinically-evaluated digital therapeutics into healthcare through education, advocacy, and research.

## BRAIN FUTURES

*Translating Science to Advance Human Potential*

BrainFutures is a national nonprofit formed to assess and advance the practical application of neuroscience research to improve human outcomes. It was launched in 2015 by the nation's second oldest mental health advocacy organization, the Mental Health Association of Maryland (MHAMD). As a citizen advocacy organization, BrainFutures offers objective assessment; public education; and a platform for policy and systems change.

## ACKNOWLEDGEMENTS

This report was authored by Nathaniel Counts, JD, Mental Health America.

Special thanks to the following individuals and organizations who provided guidance and served as reviewers for this report:

Kate Berry, America's Health Insurance Plans  
Matt Bowman, The Bowman Family Foundation  
Megan Coder, PharmD, MBA, Digital Therapeutics Alliance  
Henry Harbin, MD, The Bowman Family Foundation and BrainFutures  
Debbie L. Harrison, JD, National Business Group on Health  
Trina Histon, PhD, Kaiser Permanente, Care Management Institute  
Imtiyaz Hossain, MPH, Sage Therapeutics  
Caren Howard, Mental Health America  
Barbara Johnston, Mental Health Association In New Jersey  
Jeff Micklos, Health Care Transformation Task Force  
Natalie Navar-Mattingly, RN, BSN, Digital Therapeutics Alliance  
Theresa Nguyen, LCSW, Mental Health America  
Adam C. Powell, PhD, Payer+Provider Syndicate  
Linda Raines, BrainFutures