



Addressing Chronic Diseases, Mental Health, and Substance Use In America: Optimizing Care with Prescription Digital Therapeutics

EXECUTIVE SUMMARY

I. Introduction

On November 22, 2021, ACTION for PDTs conducted its first virtual online forum on *Addressing Chronic Diseases, Mental Health, and Substance Use In America: Optimizing Care with Prescription Digital Therapeutics*. ACTION for PDTs is a multi-disciplinary partnership that works to expand the adoption, coverage, and access to prescription digital therapeutics (PDTs) for individuals living with chronic diseases. ACTION for PDTs is led by AImed Alliance, a not-for-profit health policy organization that works to protect and enhance the rights of healthcare consumers and providers.

This virtual forum covered (1) how PDTs work and are cleared by the FDA; (2) the potential for PDTs to change the healthcare delivery system and improve patient outcomes; (3) the need for Congress to create a new Medicare benefit category for PDTs; and (4) the formation of ACTION for PDTs. The virtual forum included a presentation by AImed Alliance Counsel Stacey Worthy and Shruti Kulkarni and an expert roundtable discussion featuring Katie Archer, Director, Health & Welfare Benefits Design, Planning and Analysis at The Hartford; Dr. Andrea G. Barthwell, Medical Director at Encounter Medical Group PC and Founder and Director of Two Dream; Dr. Andrey Ostrovsky, Chief Medical Officer and Senior Vice President of Behavioral Health at Solera Health; and Dr. Zachary Zalewski, Consultant II at Avalere Health.

II. Background on PDTs

A. Prescription Digital Therapeutics Benefits, Access, and Coverage

The meeting began with a presentation from Stacey Worthy and Shruti Kulkarni of AImed Alliance, in which they provided an overview of PDTs, the benefits of PDTs, and barriers to access and coverage for PDTs.

They explained that many chronic conditions, mental health conditions, and substance use disorders are inadequately diagnosed and treated in the United States. For example, approximately 1 in 5 adults in the United States has a mental illness, but only a little more than forty percent receive treatment.¹ Likewise, 20 million patients in the United States have a substance use disorder, and yet, less than 20 percent receive treatment.² Patients can

¹ NAMI, *Mental Health By the Numbers*, <https://www.nami.org/mhstats>.

² Mary Ann Priester, et al., *Treatment Access Barriers and Disparities Among Individuals with Co-occurring Mental Health and Substance Use Disorders: An Integrative Literature Review* (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4695242/>; Substance Abuse and Mental Health Services Administration, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health*, <https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report>.

also require more complex treatments if they have co-occurring diseases. The National Institute of Mental Health has reported that half of the individuals who experience a substance use disorder will also experience a co-occurring mental illness, and vice-versa.³ In addition to the challenges of treating co-occurring diseases, many patients within large rural populations and urban health care deserts experience treatment gaps that result from shortages of treatment providers and facilities in these areas. Even where patients can receive treatment, pharmacological management alone may not be enough. Many patients may need a combination of interventions as well as additional services and support to achieve clinical benefit and encourage treatment adherence. Therefore, these patients could benefit from more accessible and innovative treatment options such as PDTs.

PDTs are a new treatment that operate at the intersection of biology and technology. PDTs are Food and Drug Administration (FDA) cleared, evidence-based tools that deliver treatment through software that is accessible via smartphones and tablets. Thus, as an FDA-cleared treatment PDTs require a prescription from a healthcare provider before they can be used. PDTs can incorporate neurobehavioral, behavioral, and artificial intelligence in their treatment programming. For example, some PDTs help patients adhere to their treatment plans through the combination of cognitive behavioral therapy, and contingency management program. Other PDTs may provide treatment for attention deficit hyperactivity disorder (ADHD) through the use of video games that target areas of the brain that require a child to focus, multitask, and prioritize information. PDTs can be used individually or in combination with other interventions.

PDTs can be beneficial because they allow patients to receive diagnostic care and treatment without traveling to a healthcare facility. In addition, the ability for PDTs to be accessed remotely can also help address social determinants of health that are heightened due to healthcare deserts.⁴ Presently, PDTs are not widely utilized, likely due to gaps in knowledge and coverage, including lack of provider knowledge of PDTs, lack of standardized insurance coding for PDTs (HCPCS), lack of Medicare and state Medicaid program coverage, and lack of private health plan coverage.

III. Expert Panel Discussion

A. FDA Approval

In laying the foundation for the expert panel discussion, Dr. Zachary Zalewski, distinguished the difference between digital health apps and PDTs. Dr. Zalewski explained that while there were thousands of digital health apps in the App Store, there were currently only seven PDTs cleared by the FDA. Moreover, unlike the thousands of digital health apps that promote and support general wellness, PDTs are specifically created and cleared by the FDA to treat diseases and disorders. Dr. Zalewski also later elaborated that the FDA-

³ National Institute of Health, *Substance Use and Co-Occurring Mental Disorders*, <https://www.nimh.nih.gov/health/topics/substance-use-and-mental-health>.

⁴ Digital Therapeutics Alliance, *Digital Therapeutics Reducing Rural Health Inequalities*, https://dtxalliance.org/wp-content/uploads/2021/01/DTA_Rural-Health_r13_110220.pdf.

clearance process provides value and legitimacy to the use of PDTs as a treatment intervention. Dr. Zalewski explained that the FDA-clearance process classifies PDTs as medical devices. He explained that this classification as a medical device is important as it demonstrates that the FDA has found reasonable assurance that the product is safe for a particular population. Further, the FDA-clearance process also permits PDTs to have FDA labeling, which helps explain (1) what the PDT is; (2) what the PDT is used to treat; and (3) who the PDT is for. Ultimately, in his view, this approval process distinguished PDTs from general digital health apps as it permits PDTs to make claims about specific outcomes.

B. PDTs Treatment of Substance Use Disorders (SUD) and During the Pandemic

Dr. Andrea Barthwell built upon the importance of PDTs being designed to treat diseases and explained that PDTs can be particularly helpful in treating substance use disorders (SUD). Dr. Barthwell explained that in SUD treatment, patients need to establish habits and patterns that help them enter recovery. She noted that PDTs can also help patients who struggle to participate consistently in treatment or face difficulty in maintaining medication compliance on their own. As a result of better pharmacologic compliance and treatment participation supported by PDT use, patients can experience overall improvements in treatment outcomes. Dr. Barthwell also explained that the use of PDTs can help bridge the care gap that often occurs when patients need assistance outside of typical office hours. For example, she explained that patient use of PDTs often shows them using the treatments between 7 PM and 7 AM, hours when providers are typically unavailable. Lastly, Dr. Barthwell stressed that PDTs are an important intervention to address the access gap in SUD treatment that often occurs in rural and underserved urban communities that lack treatment specialists.

Similarly, Dr. Andrey Ostrovsky noted how PDTs could also benefit patients who were at high risk for COVID-19 complications. Dr. Ostrovsky explained that COVID-19 will likely continue to be prevalent in the United States, thus certain patient population will need to continue taking social distancing precautions, and that PDTs could help ensure these populations receive necessary care. He also noted that for some, the switch to remote healthcare may also be a preference post-COVID-19 due to positive patient experience and/or geographic needs. Lastly, Dr. Ostrovsky underscored the need for continued research to fully understand the benefits of PDTs and to ensure that future policy positions are based on research rather than anecdotal experiences.

C. Coverage

The expert panel's discussion also addressed gaps in PDT coverage in Medicare, Medicaid, and private plans.

Dr. Ostrovsky, a former Chief Medical Officer at the Centers for Medicare and Medicaid Services, noted that there is currently a lack of research on the use of PDTs within Medicaid beneficiaries' populations. He explained that currently available PDT's are English-only, which precludes access to Medicaid beneficiaries whose primary language is

not English. Taking an equity lens, Dr. Ostrovsky encouraged manufacturers to begin to consider how PDTs can be multi-lingual to ensure minority patient communities have access to these therapeutics and to set the tone for manufacturers to consider how multi-lingual PDTs could help address health inequities.

Elaborating on the future of PDTs, Dr. Barthwell added that, as coverage increases for PDTs, providers prescribing and patients using PDTs will also increase. Therefore, in her view, there needs to be an established benefit model which covers both PDTs and the provider's time for reviewing PDT data and treatment adherence.

Dr. Zalewski echoed the need for increased coverage but also noted that there needs to be increased awareness around PDTs generally. He explained that a recent study by Avalere Health found that, out of 180 payers surveyed, 78 percent were unaware of PDTs.⁵ Further, of the 40 payers that were aware of PDTs, a limited number provided PDT coverage.⁶ The study also found that payers expected manufacturers to educate them on PDTs and advocate for their coverage.⁷ Dr. Ostrovsky added that, while payer education is necessary, provider education is equally important, as it usually takes the medical establishment many years to adopt new treatments. Dr. Ostrovsky encouraged medical professionals to educate their peers on these devices to ensure the prescription of PDTs is not biased by commercial interests.

Katie Archer, Director of Health & Welfare Benefits Design at The Hartford Financial Services, the first employer that covered PDTs, and noted that in her organization's view, covering PDTs was not only the right decision to help address behavioral health but also a strong business decision. She explained that providing coverage to accessible behavioral health treatment not only helps reduce employee absenteeism but is also key to being a good corporate partner. Further, she advised employers who were considering covering PDTs to be prepared to answer questions about the treatment, to promote conversations internally around PDT coverage, identify concerns and support for PDT coverage, and to consult with their pharmacy benefit manager (PBM). Ms. Archer encouraged employers to begin conversations with their PBMs now, as four of the largest PBMs have already agreed to cover PDTs. She noted that the process for adding coverage was as simple as adding a code to the formulary.

All panelists encouraged payers and employers, to support usage and coverage of PDTs, and for providers and medical associations to have access to PDTs and education on the benefits of PDTs for patients. Additionally, panelists noted the need for increased research on the benefits of PDTs and the inclusion of diverse populations in PDT clinical trials.

IV. Conclusion

⁵ Avalere Health, *Survey Shows Potential, Challenges and Solutions for Broad PDT Access* (Oct. 19, 2021), <https://avalere.com/insights/survey-shows-potential-challenges-and-solutions-for-broad-pdt-access>.

⁶ *Id.*

⁷ *Id.*

In conclusion, the ACTION for PDTs multidisciplinary partnership will be working both proactively and reactively with partners to improve access and coverage of PDTs. Future ACTION for PDTs activities includes submitting a sign-on letter to Congress on coverage for PDTs; submitting a letter to CMS encouraging the creation of a HCPCS code for PDTs; and hosting a second webinar on PDTs, likely in March 2022. Individuals or organizations interested in learning more about or joining ACTION for PDTs may email policy@aimedalliance.org.