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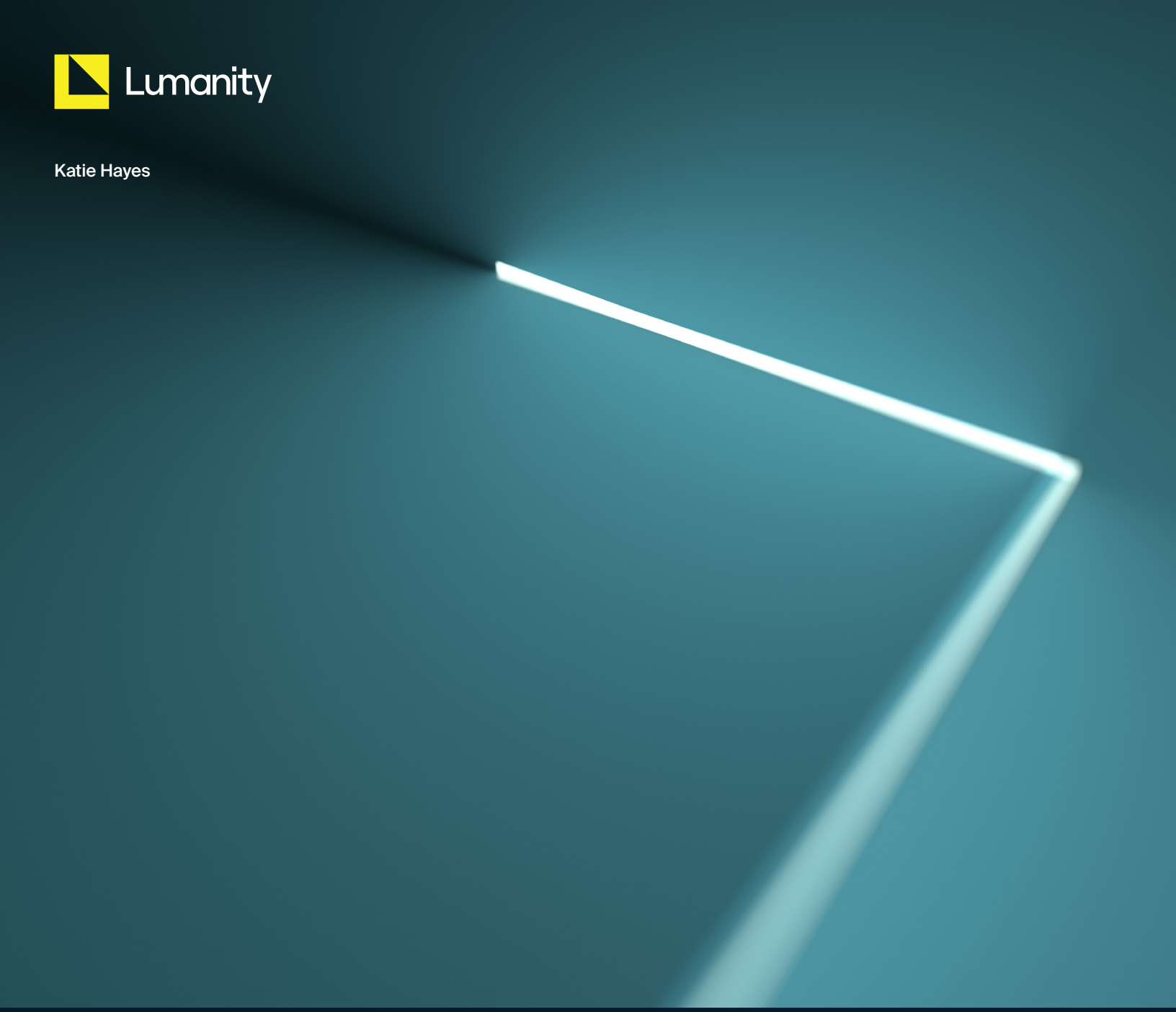

The Transformative Potential of Digital Therapeutics in Mental Health Care Delivery

Digital solutions may enable a triple win

Technology has long been a driving force behind innovation in health care. While mental health care has been overlooked in the past, digital therapeutics (DTx) are bound to change that.

Mental health care is fragmented, with few providers having complete insight into the patient across the treatment continuum. This is in part due to the severe shortage of mental health care professionals, which leaves providers increasingly overextended with limited resources. By the end of 2024, the United States will face a shortage of 14,280 to 31,109 psychiatrists, with psychologists, social workers, and other providers also in short supply.[1,2]

Studies of the impact of the COVID-19 pandemic on mental health have highlighted barriers to care. In 2021, a Kaiser Family Foundation national survey of 1,862 adults seeking mental health services found that approximately 1 in 4 respondents could not afford the cost of these services, and 1 in 4 could not find a mental health provider.[3] Although these barriers preceded the pandemic, they continue to challenge individuals who seek care. More than 2 out of 5 Americans live in areas with a shortage of mental health providers.[4] Of patients seeking mental health treatment, 31% have had mental health care appointment wait times longer than one week.[5] More importantly, individuals must often contend with the stigma long attached to mental illness that may deter them from seeking care in the first place.

In response to these significant barriers, a variety of software-as-a-medical-device (SaMD) options have emerged to help address the unmet needs in mental health care. Wellness applications and wearable solutions jump-started the wave into what's known as DTx. As evidence began to show better outcomes, pharmaceutical manufacturers partnered with software companies to create treatment modalities that function across a wide spectrum. With an estimated 137 DTx products currently in the pipeline, the DTx market is expected to reach $56 billion by 2025.[6,7]

Prescription digital therapeutics (PDTs) are a subset of DTx, designed to treat a specific medical condition. Like prescription pharmaceuticals, PDTs require substantial clinical trial evidence proving safety and efficacy for FDA authorization following the De Novo classification process or 510(k) premarket notification process. As such, outside of special circumstances, PDTs become prescription-only products. The PDT market is rapidly expanding, and according to Lumanity's review of publicly available sources, some 46 PDTs could be on the market within the next few years, including 26 currently available products and 20 in late-stage development.

PDTs serve as an extension or parallel option to conventional, standard-of-care treatment and may help alleviate various access barriers. For many individuals, the stigma associated with seeking mental health care can be an obstacle to overcome. PDTs allow patients to receive treatment through the anonymity of their smart devices, offering convenience and privacy.[8] "Some may point to the fact that not everyone will be able to benefit from digital therapeutics, because of lack of a smartphone or access to broadband," said Voytech Sudol, AVP, Market Access at Lumanity, who has been closely monitoring the DTx market since its inception. "The reality is that even among 50- to 64-year-olds, 83% own a smartphone.[9] More importantly, about 93% of the US population has Internet access.[10] Even in the very unlikely event that you have neither a smartphone nor access to the Internet, it would likely still be easier to access mental health care via a PDT at your local public library than trying to find an available mental health provider within a two-hour drive."

Even though the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 requires health plans that offer mental health and substance abuse disorder benefits to ensure that the financial requirements are no more restrictive than those on medical and surgical benefits, access to mental health care remains elusive. Congress has debated adding reforms to increase parity enforcement, but without the infrastructure in place that can appropriately manage workforce limitations and improve coordination of mental health within primary care, these reforms may not improve access.[11] "PDT products address these challenges in that they allow patients to access treatment irrespective of location.

Additionally, PDTs can drive treatment satisfaction and improve adherence, which have been proven to lower health care utilization. All of these things then roll up to better outcomes and lower costs for the health plan," said Sudol. "Plus, because PDTs hit many of these quality measures, it makes payer health plans more marketable."

Rating systems and performance measures serve as important evaluation techniques that enable enrollees to appropriately compare plans while holding payers accountable. PDTs have been linked with positive patient engagement and satisfaction, which are key measures of the Consumer Assessment of Health Care Providers and Systems (CAHPS) survey.[12] Results of the CAHPS survey, along with the Health Care Effectiveness Data and Information Set (HEDIS) measures, the Health Outcomes Survey (HOS), and other data sources, inform the Centers for Medicare & Medicaid Services' star ratings.[13] Medicare plans with fewer than 3 stars are considered poor quality and unlikely to provide optimum health care options.[14] Plans that achieve 5 overall stars have an enrollment advantage—enrollees can switch to a 5-star plan at any time between December 8 and November 30, bypassing the typical enrollment period.[15] As payers face continued scrutiny of their plans' performance scores, PDTs offer a potential way for payers to improve scores.

PDTs are particularly suited to fulfilling expectations of quality measures because they are designed to generate and share data across stakeholders. In fact, according to Sudol, payers may be able to obtain and analyze patient-level data without identifying a specific patient.

With PDTs, patients experience a multitude of benefits, which often stem from features not available with conventional medicine. "Take mental health as an example," says Sudol. "Payers themselves recognize that the PDT-specific benefit of stigma reduction could result in better adherence, fewer in-person visits, and less hospital care utilization. All of that could lead to lower health care costs while improving clinical outcomes. In fact, for the first time in history, PDTs may enable us to create a 'triple win' situation in health care: Patients will be satisfied with their care, payers will improve their quality measure scores, and the entire health care ecosystem will experience lower financial burden."

According to Lumanity's meta-analysis of surveys conducted with more than 450 payer decision-makers, compared with only a year ago, payers increasingly recognize the urgency of establishing coverage for DTx products, especially in mental health, diabetes, and cardiology. PDT development and awareness have grown exponentially over the past year. A year ago, the pharmacy and therapeutics (P&T) committee evaluation process was relatively informal and undefined. Depending on the DTx product, surveyed payers oscillated between medical, pharmaceutical, or digital review processes. "What we're seeing is that a year ago, there was a severe lack of clarity as to how DTx and PDTs should be categorized and evaluated," said Sudol. "The newness of the market resulted in a lot of ad hoc reviews. Now, after most organizations have had a chance to review 15 to 20 digital therapeutics, they have begun to land on a concrete evaluation process. They also seem to realize that while the pharmacy benefit model is usually most appropriate, some PDTs, such as diagnostics, may be better served by medical benefit reviews."

While some payers have developed clear pathways for PDT review and discern the differences between medical and pharmaceutical review processes, stakeholders involved in P&T committees may lack sufficient technology-related expertise, so additional subject matter experts may be needed, according to Sudol.

"It is critical for payers, providers, manufacturers, and regulatory organizations to further align to guarantee patient access and address the unmet needs in mental health care," Sudol added. "Time and time again, technology has been proven to improve human life. Consider the discovery of ultrasound and the impact it has on prenatal diagnostics today—or next-generation sequencing and its impact on cancer treatment and prevention. Examples like these abound in the medical field, and yet, all of them were originally seen as unnecessary incremental expenses and burdens on the health care system and often took years to be seen as valuable."

As the digital health market grows to $1.5 trillion by 2030, it will inevitably change the delivery and quality of health care.[16] However, given the breadth and newness of digital therapeutics, the adoption speed will be dictated by high-quality, effective communication among the market stakeholders to ensure that these treatments are quickly accessible to appropriate patients at the right price.

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