FAST*facts*

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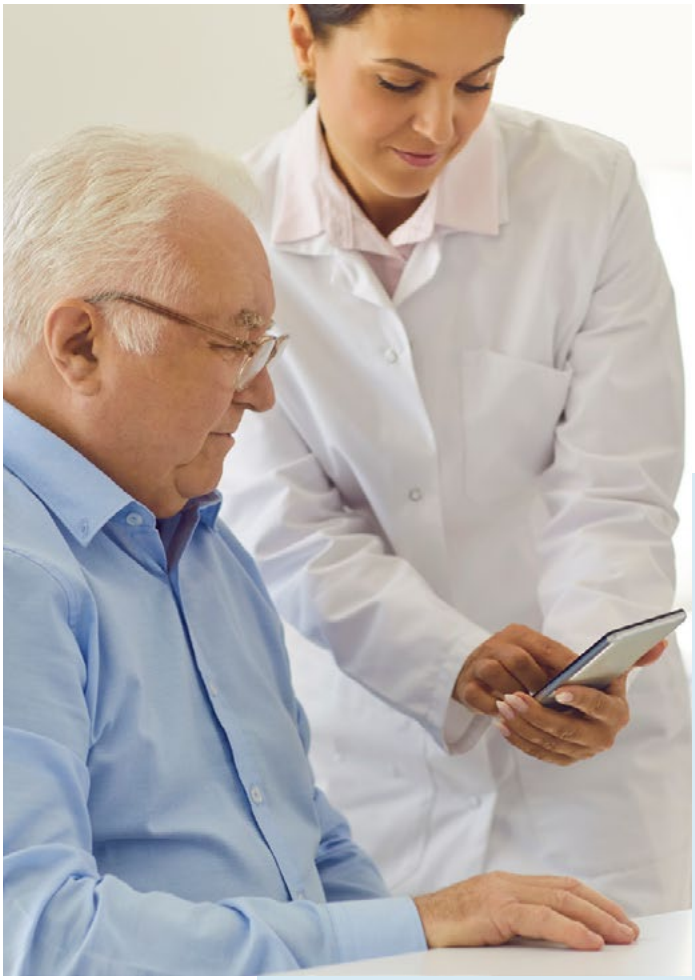
PRESCRIPTION DIGITAL THERAPEUTICS (PDTs)

In today's technologically advanced world, devices and apps are changing the way people manage their health. One example of how technology and health care are fusing to fuel better outcomes for patients is a field of technology known as prescription digital therapeutics, or PDTs.

Q: What are prescription digital therapeutics?

Prescription digital therapeutics (PDTs) are software-based applications to prevent, manage or treat mental or physical conditions. They have been approved by the U.S. Food and Drug Administration as medical devices following clinical trials that proved both their safety and efficacy.



In some ways, available prescription digital therapeutics are similar to many downloadable wellness apps that people use on their own. But they are more reliable because they have been designed and developed with clinically validated tools and data, and go through the rigorous FDA approval process like other medical devices. They have also been subject to peer review to ensure that they yield medically meaningful outcomes.

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Q: How do prescription digital therapeutics get approved? What diseases are they approved to treat?

Before prescription digital therapeutics (PDTs) reach patients, they must be approved by the FDA. FDA approval requires developers to submit data from superiority trials, which should show that prescription digital therapeutics have a meaningful, positive difference from other treatments. Submissions are either for the de novo or 510(k) review pathways. The de novo pathway is for novel, low-to-moderate risk products, while the 510(k) pathway is for products whose safety is comparable to already-approved products. Some prescription digital therapeutics are subject to randomized controlled trials.

Nine prescription digital therapeutics are currently FDA approved. These are for treatment of Type II diabetes, substance and opioid use disorder, PTSD-driven traumatic nightmares, attention deficit hyperactivity disorder, insomnia, irritable bowel syndrome, chronic lower back pain, and decreased eyesight.

Q: How are prescription digital therapeutics used by patients and health care providers?

These therapeutics (PDTs) can be used as part of a traditional course of treatment or as an effective alternative for treating issues that depend on routine behavioral adherence, such as substance use disorders or mental health conditions.

Prescription digital therapeutics augment face-to-face visits and treatments by communicating patient updates to providers, formularies and coding systems in real time. They must be prescribed as part of a course of treatment.

Q: How do patients and providers benefit?

Prescription digital therapeutics (PDTs) engage patients and encourage them to follow a prescribed course of treatment by tracking their daily progress. Health care providers can remotely monitor a patient's progress and analyze real-time data and insights from their everyday lives. Rather than asking a patient about his or her progress between office visits, providers can remotely monitor and provide care to patients, allowing people to access treatment anytime, anywhere.

In a survey of health care and life sciences professionals, 63% stated individualized care was one of the main benefits of prescription digital therapeutics, while 61% said greater patient engagement.[1]

Q: How do prescription digital therapeutics improve efficiency?

For health care providers and facilities, prescription digital therapeutics (PDTs) can reduce overhead and administrative costs by eliminating unnecessary office visits, helping patients progress between visits, increasing treatment efficiency and improving overall health outcomes. One study of prescription digital therapeutics for opioid use disorder found the programs saved health care systems $2,385 per patient over a six-month period.[2]

They also help ease the burden on health care facilities and providers during times of increased demand.

For example, during COVID-19 shutdowns, health care providers, especially mental health professionals, were able to use prescription digital therapeutics and telehealth platforms to offer safe, socially distanced appointments that patients otherwise may have missed.

Q: Which patients will benefit?

Although anyone can benefit, prescription digital therapeutics (PDTs) are particularly helpful for reaching rural and underserved communities. For example, about 62% of non-metropolitan counties have no Diabetes Self-Management Education and Support program, so making prescription digital therapeutics available to help patients with diabetes track their food choices and glucose levels would likely be rewarding.[3]

In one example, prescription digital therapeutics supported cognitive behavioral therapy for patients with diabetes as they tracked their food choices and glucose levels. Program completers lost a mean 4.9% of baseline body weight after one year.[4]

Adult mental health patients and other behavioral health patients may also find prescription digital therapeutics particularly helpful. Out of 180 clinical trials for prescription digital therapeutics, more than 40% were in areas broadly defined as mental health, including psychiatry, addiction, neurology and sleep medicine.[5]

Q: What access barriers exist?

One barrier is simply low awareness. Many health care providers still need to be educated about the new technology. The American Medical Association, for example, reports that only 22% of physicians have prescribed them.

Adoption may be inconsistent in some areas, even if they are actually available.[6]

Logistics may also pose a challenge. Although most current prescription digital therapeutics (PDTs) are downloadable like any other smartphone application, they require a prescription from a health care provider. A product activation code may be dispensed to patients by a third-party vendor, such as a pharmacy.[7] Prescription digital therapeutics in development may use additional hardware such as sensors and virtual reality headsets and other wearables. These would likely be delivered to patients' homes by a vendor or direct from the manufacturer.

Q: What other barriers are there?

Providers have historically been hindered from prescribing patients prescription digital therapeutics (PDTs) because, until recently, they had no billing codes with the Centers for Medicare and Medicaid Services. Meanwhile, Medicaid coverage continues to be a major barrier for many Americans who would benefit from prescription digital therapeutics. Coverage varies from state to state and, in most, express legislation would be required to authorize coverage by Medicaid.

Private insurers have likewise been slow to integrate prescription digital therapeutics, though they are increasingly doing so. One common misconception is that prescription digital therapeutics are "experimental," despite their having received approval from the FDA after a rigorous review process.

Regulatory challenges also exist. The Prescription Digital Therapeutics to Support Recovery Act (S. 3532) was introduced in the U.S. Senate in March 2020, but the bill was not taken up. Legislators are expected to revisit the issue in 2022.

One additional concern is possible patient reluctance due to privacy and security concerns, but prescription digital therapeutics are subject to the Health Insurance Portability and Accountability Act, or HIPPA, which provides strict protections for personal health information.

Q: How might prescription digital therapeutics help patients in the future?

A handful of prescription digital therapeutics (PDTs) are currently available to treat chronic mental, behavioral and cognitive disorders. These include conditions such as opioid use disorder, depression, chronic insomnia, and attention deficit hyperactivity disorder.

Meanwhile, nearly 150 FDA-regulated prescription digital therapeutics are expecting clinical trial results in 2022.[8] Other programs now in development will rely on more sophisticated hardware devices such as sensors, wearable and wireless devices, virtual reality headgear, and diagnostic products. These devices will be able to monitor vitals and address more dynamic conditions like blood and circulatory disorders, respiratory disorders, and nervous system disorders.

CONCLUSION

Though policymaking and public awareness need to catch up with reality, prescription digital therapeutics are clearly here to stay. For now, the applications are elegantly simple, though they may become more complex and sophisticated as they become more popular.

Prescription digital therapeutics will help streamline and synchronize patient-centered care so that diagnosis, treatment, and follow up are all one seamless, real-time experience between providers and their patients. This synthesis will alleviate crowded waiting rooms and save dollars that can be used elsewhere in the health care system.

Building on digital prescription therapeutics' usefulness in treating chronic mental, behavioral and cognitive disorders, evolving technology and growing awareness stand to increase the number of diseases and patients that doctors can treat with prescription digital therapeutics.

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